EXERCISE-BASED COGNITIVE THERAPY AS A NOVEL TREATMENT FOR INSOMNIA AND DEPRESSION

by

Kristin Lamb Daley

A dissertation submitted to the faculty of
The University of North Carolina at Charlotte
in partial fulfillment of the requirements
for the degree of Doctor of Philosophy in
Health Psychology

Charlotte

2010

Approved by:

_____
Dr. Virginia Gil-Rivas

_____
Dr. Jane Gaultney

_____
Dr. Amy Peterman

_____
Dr. Jan Warren-Findlow

_____
Dr. Kelly Zellars

ABSTRACT

KRISTIN LAMB DALEY. Exercise-based Cognitive Therapy as a novel treatment of insomnia and depression. (Under the direction of DR. VIRGINIA GIL-RIVAS)

The present study introduces a new treatment modality for comorbid insomnia and depression that combines cardiovascular exercise and elements of cognitive behavioral treatment: Exercise Based Cognitive Therapy (EBCT). While simultaneously performing moderate - high intensity cardiovascular exercise, participants were instructed to focus on problems, goals and negative automatic thoughts. The key principal of EBCT is the combination of focused problem solving with physical activity. This intervention targeted individuals in a common workplace who self identified as needing assistance with stress management. The intervention involved 12 sessions, increasing in cardiovascular intensity with each successive session. Study participants completed several psychological and sleep measures pre- and post-intervention. After three months, participants completed qualitative feedback of their overall experience.

A total of 18 individuals participated in the intervention, all female, mean age 39.4 years (*SD* =9.04). On average, participants attended 5.00 (*SD*=3.74) sessions. Participants were predominantly Caucasian (72.2%), and a majority had a college education or beyond (55.5%). ANCOVAs were conducted to assess changes in the outcomes of interest. Tests of within-subjects effects demonstrated significant improvements in depression, insomnia, total sleep time, sleep latency, sleep efficiency, anxiety, perceived stress, automatic negative thoughts, and coping self-efficacy. Number of sessions attended was a significant covariant for the models for sleep latency, sleep

efficiency, and coping self-efficacy. In contrast the number of sessions attended did not predict the magnitude of changes in anxiety and depression. Qualitative feedback had a 78.6% response rate; 100% of the respondents indicated the intervention was beneficial.

This study presents the first investigation in which principles of psychotherapy were combined with physical exercise as a treatment approach to comorbid insomnia and depression. This new treatment modality was acceptable to participants, and demonstrated that a non-pharmacologic approach can have positive effects, simultaneously, on sleep, anxiety and depression. The ease with which the protocol was administered demonstrates that it may be attractive to patients and clinicians as an alternative to more formal psychotherapy or more informal general recommendations to increase physical activity.

ACKNOWLEDGEMENTS

First of all, I would like to acknowledge Dr. Virginia Gil-Rivas for the time, energy, and resources that she has devoted to me through her time as my mentor. She has been willing to review a number of drafts and projects, and worked to assist me in receiving all of the equipment required for the completion of this project. I would also like to thank Dr. Jane Gaultney for being willing to assist in the acquisition of actigraphs for the performance of this study. It is also important to acknowledge the personnel and directors of Charlotte Eye, Ear, Nose & Throat, Assoc., PA. In particular, Annett Potts, director of Human Resources, has proven herself to be an amazing ally in the completion of this and other research studies within the bounds of the practice. Dr. M. Susan Esther has been a wonderful guide through my forays into the study of sleep medicine, and has connected and guided me through the early days of my career. Finally, I would like to thank my family for their tireless support of my studies. In particular, there are no words to express the support that my husband, Jeff Daley, has provided me through the many steps of the completion of this dissertation. Embarking on this path fulfilled my father's dream for me, and I really wish he could have seen me complete it.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

Sleep disorders and mood disorders have a definite relationship, in both symptoms and potential for overlying treatment. Thirty-one percent of patients with insomnia had an episode of major depressive disorder at some point in their lifetime, as compared to 2.7% of patients with no sleep complaints (Benca, 2005). Most individuals with major depressive disorder (MDD) report poor overall sleep, with worsening reported sleep in direct relation to the severity of depressive symptoms (Smith, Huang, & Manber, 2005). Although the relationship between insomnia and depression is often acknowledged by both sleep and mental health professionals, treatment efforts historically have been focused on either disorder, rather than both (Manber et al., 2005). If not addressed, insomnia symptoms persist even beyond treatment of depression. In prospective studies of insomnia and depression, consistent insomnia was observed at five and seven year follow-ups when treatment had only focused on depressive symptoms (Jindal, Buysse, & Thase, 2005).

The present study introduces a new treatment modality for people with comorbid insomnia and depression that combines cardiovascular exercise and elements of cognitive behavioral treatment: Exercise Based Cognitive Therapy (EBCT). While simultaneously performing moderate to high intensity cardiovascular exercise, participants are instructed to focus on current problems, goals and the negative automatic thoughts that may be associated with these problems. The principal of EBCT is the combination of focused

problem solving with physical activity, which is expected to result in improved mood as an immediate outcome. In the long term, participants in this intervention will develop the ability to utilize physical exercise as a way to cope with negative emotional states. This intervention will be targeted toward individuals in a common workplace who self identify as needing assistance with stress management, and who potentially may be suffering from depressed mood and insomnia symptoms.

The initiation of a moderate to high intensity cardiovascular exercise regimen combined with elements of cognitive behavioral therapy is intended to decrease insomnia and depressive symptoms, and additionally improve self-efficacy and self-esteem. The EBCT treatment may potentially be effective with a variety of emotional and physical disorders, but it may be particularly helpful with stressed individuals because it combines emotional work with physical activity- both treatment modalities that are individually utilized in stress management, depression, and insomnia treatment. The specific aims of the study were the development of the EBCT protocol, and demonstration that the protocol could be performed as designed, resulting in reduced psychological stress, improved mood and insomnia symptoms.

Depression

Depression remains the leading psychological disorder in the United States. According to an epidemiological study of psychiatric disorders, 9.5% of American adults suffer from depressive illness every year (Kessler, Chiu, Demler, & Walters, 2005). Depression is debilitating in many ways, and can result in varying forms of disability through the lifespan (Baune, Adrian, & Jacobi, 2007). Major Depressive Disorder (MDD) results in role impairment in 50% of depressed patients, which includes inhibited ability

to perform professional and personal responsibilities (Ebmeier, Donaghey, & Steele, 2006). The World Health Organization has identified MDD as one of the most disabling medical conditions in the world (as cited by Leykin et al., 2007). Depression is an illness with a relapsing and remitting pattern, in which most patients experience some degree of decrease in symptoms in a given length of time with an eventual likelihood of reoccurrence (Katon et al., 2002).

The causes of depression are a complex interaction between physiology, behavior, and environmental conditioning. Structural brain differences observed in depressed patients include hippocampal atrophy and observed differences in the anterior cingulate, orbitofrontal cortex, dorsolateral cortex, striatum, and medial temporal lobe (Ebmeier, Donaghey, & Steele, 2006). Heritability of depression is estimated at 40%, with an understanding that there are likely multiple gene mechanisms that result in vulnerability toward depressed mood. Serotonin transporter genes are currently the prevalent heritable modality under investigation, but there is much to be discovered in the biological basis of depression (Ebmeier et al., 2006). Beck's cognitive theory of depression, in which a biological or psychological predisposition toward depression is "triggered" by an environmental or interpersonal stressor, remains the predominant explanation (Oei, Bullbeck, & Campbell, 2006). Anxiety and depression are closely related, and depression diagnoses often incorporate the features of anxiety (Andrews, Hejdenberh, & Wilding, 2006).

Depression treatments have evolved over time, with a major emphasis in pharmaceutical advancements. There has been a boom in the production and development of anti-depressant medications in the last few decades, resulting in an arsenal of available

medication treatments for patients. In a study of anti-depressant usage from 1994 to 2000, Kivimaki et al. (2007) found that usage had doubled in this time period. The authors concluded that this pattern represented a change in provider prescriptions rather than a significant increase in number of depressed patients. Medications should not always be the first treatment choice in all cases, however, because there can be significant negative effects and some patients are unwilling to take medication (Ebmeier et al., 2006). The most prevalent side effects associated with these medications include anxiety, irritability, and insomnia. Furthermore, approximately 40% of depressed patients treated with anti-depressant medication in a primary care setting do not reach adequate symptom reduction (Katon et al., 2002).

Psychological therapies to treat depression, including Cognitive Behavioral Therapy (CBT), Interpersonal Therapy (IPT), and Problem-Solving Therapy (PST) have been utilized over time with demonstrated efficacy in long-term reduction of depressive symptoms (Ebmeier et al., 2006). Cognitive Behavioral Therapy was initially developed by Aaron T. Beck and works to counter the negative cognitions that perpetuate the depressive state (Oei et al., 2006). For some of these treatments (CBT and PST) efficacy was equivalent to that of treatment with anti-depressant medication (Ebmeir et al., 2006; Pierce & Gunn, 2007). Unfortunately, some general provider resistance toward referral for psychotherapy has been demonstrated and hypothesized to be related to a reduction in control over patient's treatment; general practitioners are concerned that referral for psychotherapy will reduce the number of patient interactions with the provider (Pierce & Gunn, 2007). It is also likely that patients may be resistant toward referral for psychotherapy as well.

Psychological interventions can be effectively performed in both individual and group settings, which allows for greater treatment dissemination with lower associated cost. Studies of the efficacy of CBT group therapy have been able to demonstrate that depressive symptoms, automatic negative thoughts, and depressed feelings are reduced with the completion of structured CBT group therapy (Oei et al., 2006).

Depression can differ in symptom severity, which can be an additional factor in response to treatment. Severe depression is much more difficult to treat, and often does not easily respond to traditional interventions. In a study of additional support methods for increasing treatment adherence and reducing longer term depression severity, Katon et al. (2002), found that additional psychiatric support in the form of bi-weekly phone calls reduced symptom severity in moderate depression, but was ineffective in patients with severe depression. Patients with severe depression often have significant sleep disturbance, and there has been some evidence that addressing the sleep disturbance can be effective in achieving some level of remittance. Dalton, Rotundi, Levitan, Kennedy, and Brown (2000) found that there was a 20% reduction in symptoms among patients with severe depression who received melatonin treatment in an attempt to regulate sleep pattern. Patients with severe, recurrent depression often have been through several failed medication attempts, and prior medication failure is indicative of poorer response to any new medication introduction (Leykin et al., 2007). Patients with medical illness have increased risk of greater depression severity (Baune et al., 2007; Katon et al., 2007). However, high rates of physical activity can be protective in the midst of medical illness and negative life events. Harris, Cronkite and Moos (2006), found that while medical illness tended to increase concurrent depression by one point, higher levels of physical

activity reduced depression by 0.9. An active individual with four medical conditions would be as likely to be depressed as a sedentary individual with two medical illnesses. Treatment of depressive symptoms has often been found to decrease symptom report for chronic medical conditions (Katon et al., 2007). In sum, there is room for the creation of new treatment approaches to depression.

Although anti-depressant medication is a primary treatment for depression, there are many reasons why other treatment modalities may be attractive to patients with depression. In a study of treatment modality preference, Lin et al. (2005) demonstrated that there are differences in patient populations who prefer psychotherapy over anti-depressant medication. Patients were more likely to demonstrate a preference toward psychotherapy when they had no prior experience with anti-depressant medication and were not Caucasian. This group of patients demonstrated a general preference for psychotherapy over antidepressant treatment (24% versus 16%) when selecting monotherapy over combined therapy (Lin et al., 2005). Negative experiences with antidepressant medication and a desire to be free of a medication regimen are factors that move patients toward non-pharmacologic treatment. The side effects of medication include: dry mouth, constipation, bladder problems, sexual problems, blurred vision, drowsiness, headache, nausea, insomnia, and agitation (Hollan, Thase, & Markowitz, 2002). Any of these side effects can be disturbing for patients and can result in medication termination regardless of depressive symptoms. Long-term treatment efficacy relates significantly with patient preference, and patients are more likely to report long-term reduction (12 months) in symptom severity when their treatment regimen has been matched to their preference (Lin et al., 2005). Interestingly, prior experience with

medication failure makes successful treatment with medication less likely (Leykin et al., 2007). Cognitive Behavioral Therapy has demonstrated efficacy in symptom reduction for depression, even in the case of prior failed treatments (Leykin et al., 2007).

Depression presents challenges from both the epidemiological/incidence and treatment perspectives. The demand for a wider variety of effective treatments allows for much growth and innovation in mental healthcare. A primary goal of this planned treatment intervention is to allow for the introduction of a treatment intervention that will address depression in an innovative manner.

Insomnia

Sleep is dynamic in that it is both an active and a passive process, with cycles of brain activity alternating between high and low activation levels. Sleep is believed to serve many primary functions for the body, which include the reestablishment of depleted energy stores, the opportunity for tissue repair, conservation of physical energy, and the ability to down-regulate body temperature (Youngstedt, 2005). Insomnia is a complaint of insufficient or inadequate sleep, related to the inability to initiate or maintain sleep (Benca, 2005). The experience of insomnia is subjective, as the amount and quality of sleep required varies between individuals (Benca, 2005). Insomnia affects between 30% and 50% of the United States population based upon subjective self-report and approximately 10% of the population when using the strictest diagnostic criteria for chronic insomnia (Zorick & Walsh, 2001). Insomnia is most prevalent in female and elderly populations, with approximately 50% of people over the age of 65 reporting an insomnia-like complaint in the past year (Zorick & Walsh, 2001). Insomnia commonly follows a relapsing and remitting pattern, which persists over time without treatment

(Jansson-Frojmark, & Lipton, 2008). Unfortunately, insomnia is commonly viewed as an aspect of physiological or psychological distress, and physicians often neglect taking a comprehensive sleep history during general patient examinations (Holbrook, Crowther, Lotter, Cheng, & King, 2000).

Normal sleep consists of physiological drives toward de-arousal, sleep stimulus control, homeostatic drive toward sleep, and circadian rhythm (Benca, 2005). Key factors in sleep assessment include sleep efficiency, calculated as the amount of sleep time divided by time spent in bed; sleep latency, the amount of time it takes a person to fall asleep; and sleep disruption, which is often calculated as number of disturbances (i.e., apnea, leg movements or arousals) divided by sleep time (Hauri, 2000). Insomnia arises from predisposing, precipitating, and perpetuating factors, which work in concert to disrupt the normal drives toward sleep. Predisposing factors for insomnia include potential genetic and familial factors that increase likelihood of high states of arousal and tendency toward excessive introspection. Precipitating factors can be periods of intense stress, increased time demands, and major changes to routine. Perpetuating factors include the behaviors and maladaptive thought patterns that can cause insomnia to persist. When perpetuating factors are not present, the drive toward homeostasis will usually correct the sleep cycle back toward a normal rhythm (Benca, 2005).

There is a primary relationship between sleep, illness, and behaviors. The effects of insomnia include sleepiness, fatigue, muscle aches, depression, and lack of concentration and alertness (Benca, 2005). Insomnia results in increased irritability, poor immune functioning, and increased risk of psychological and physical illness (Hauri, 2000). Insomnia leads to difficulties with all aspects of daily functioning. Poor sleep has

been linked to poor physical health, memory, and work performance, problems with interpersonal relationships, impaired concentration, difficulty accomplishing tasks, diminished coping ability, and increased risk of mortality (Altena, Van Der Werf, Strijers, & Someren, 2008; Cheek, Shaver, & Lentz, 2004). Older adults who demonstrate poor sleep efficiency at night demonstrate very low activity levels during the day, which can contribute to greater overall decline in physical health (Tanaka & Sirakawa, 2004). Poor health can also be a precipitating factor in the incidence of insomnia, which can then be reinforced by maladaptive behavior changes (Benca, 2005).

Incorporating an understanding of insomnia development, sleep hygiene consists of the principles and behaviors that have been established as a recommendation to maximize sleep quality and continuity. There are four major subcategories in sleep hygiene: homeostatic drive for sleep, circadian factors, drug effects, and arousal in sleep setting (Zarcone, 2000). The interventions for sleep hygiene incorporate stimulus control, temporal control, and sleep restriction (Holbrook et al., 2000). Stimulus control can be critical, because excessive negative thoughts and rumination at bedtime have been significantly associated with disturbed sleep (Benca, 2005). Temporal control incorporates the development of chronological consistency in daily routines, which helps to maximize circadian sleep drives (Holbrook et al., 2000). For example, creating the same pattern of bedtime, mealtimes, and even exercise time creates a consistent circadian pattern, which increases sleep drive at the desired bedtime. Sleep restriction therapy involves strict limitation of time in bed, which additionally maximizes the drive for sleep (Benca, 2005). Regular physical exercise is considered essential in increasing the

homeostatic drive for sleep, and can also assist with circadian rhythm establishment and regulation (Zarcone, 2000).

Sleep hygiene principles are often used to understand the cause of an individual patient's insomnia and as a potential behavioral treatment, but have not been empirically validated as a sole treatment for insomnia (Morin, 2005; Stepanski & Wyatt, 2003). Although sleep hygiene guidelines are often explained to patients, the expectations for their efficacy, or that the patient will actually adhere effectively to the guidelines are minimal (Cheek et al., 2004). Often, changes in sleep routine are viewed as too difficult for the patient to maintain, and alternative treatment modalities are employed in addition to sleep hygiene (Cheek et al., 2004). In a study that directly compared sleep hygiene with another empirically validated treatment, sleep hygiene demonstrated minimal symptom improvement (Edinger et al., 2008).

Ideal treatment of insomnia is multi-factorial, with often a hypnotic medication prescribed in the early portion of treatment, followed by behavioral, cognitive, and environmental adaptations to alter the sleep patterns (Jindal et al., 2004). Pharmaceutical treatment is commonly employed because of the almost immediate initial response to treatment (Zorick & Walsh, 2000). A study of the prescription habits of general practitioners demonstrated that 46% of the physicians surveyed identified pharmacologic treatment of insomnia as the primary treatment, often after only asking a mean of 2.5 sleep-related questions (Everitt, Avorn, & Baker, 1990). Unfortunately, the response to pharmaceutical treatment usually dissipates with habituation and often is accompanied by undesirable side effects (Zorick & Walsh, 2000). Medications are not recommended for long-term treatment, and most medications lose their efficacy significantly within one

month of consistent use (Zorick & Walsh, 2000). For patients who are taking many medications, there is often concern that the addition of pharmacologic treatment for insomnia will interfere with the patient's current medication regimen (Zorick & Walsh, 2000).

When pharmacologic treatments are compared with behavioral treatments for insomnia, behavioral treatments demonstrate significantly greater long-term efficacy (Jindal et al., 2004). Cognitive behavioral therapy for insomnia (CBT-I) has emerged as a new treatment that has some empirical validation of its efficacy, but validation in people with comorbid disorders has been limited (Edinger et al., 2009; Smith et al., 2005; Wang, Wang, & Tsai, 2005). Preliminary studies of treatment efficacy for CBT-I demonstrated a thirty percent symptom reduction with improvements maintained for a one year period (Smith et al., 2005). Surprisingly, in one trial of CBT-I in a group of participants that include people who regularly used hypnotic medication, Zavesicka, Brunovsky, Matousek and Sos (2009) found that there was even greater improvement in sleep efficiency and wake after sleep onset parameters after the discontinuation of hypnotic usage. Furthermore, discontinuation of hypnotic usage in a tapered withdrawal was associated with significantly increased feelings of self-efficacy and health-related quality of life (Belleville & Morin, 2008). Trials of benzodiazepines, a commonly prescribed sleep medication, have demonstrated minimal changes in sleep gained with their use, and the improvement in sleep observed with exercise as primary treatment was found to be equivalent in effect (Holbrook et al., 2000). Finally, one of the conclusions of a National Institutes of Health (NIH) State-of-the-Science investigation was that there is a dearth of evidence for long-term efficacy in most treatments of insomnia, both pharmacologic and

other modalities (NIH, 2005). Treatment of insomnia is not formulaic and there is much room for more treatment options.

Comorbid Depression and Insomnia

Independently, MDD and insomnia are major public health problems in the United States. However, the presence of insomnia within MDD presents a health crisis that is noteworthy. People with insomnia are two to three times more likely to have a psychological disorder, with risk for depression four times as likely (Zorick & Walsh, 2001). Anxiety also has a significant relationship with insomnia, with 60% of people with social phobia and 68% of people with panic disorder experiencing insomnia (Ziwi, Shawe-Taylor, & Murray, 2005). Patients with depression who also report sleep problems demonstrate significantly worse outcomes in symptom severity, response, remission and treatment attrition, as compared to those with normal sleep profiles (Zorick & Walsh, 2001). Additionally, sleep complaints worsen response to pharmacotherapy for depression and decrease the time course to relapse (Manber et al., 2005). Insomnia affects the stability of response to depressive treatment, with two thirds of patients with persistent insomnia at the end of depression treatment experiencing relapse of major depressive episodes within one year (Smith et al., 2005). In a comparison of older adults with and without insomnia, older adults with insomnia had significantly higher scores on the Beck Depression Inventory and greater state and trait anxiety, as measured by the State-Trait Anxiety Inventory (Morin & Gramling, 1989).

There are many studies that have demonstrated significant relationships between insomnia and depression in patients with initial primary features of either disorder (Besiroglu, Agargun, & Inci, 2005; Breslau, Roth, Rosenthal, & Andreski, 1996;

Cukrowicz, Otamendi, Pinto, Bernert, Krakow, & Joiner, 2006; DeGennaro, Martina, Curcio, & Ferrara, 2004; Ford & Cooper-Patrick, 2001; Perlis, Giles, Buysse, Tu, & Kupfer, 1997; Riemann & Voderholzer, 2003). Prospective studies have demonstrated that insomnia can be a reliable predictor of the incidence and relapse of depression (Breslauet al., 1996; Buysse, Angst, Gamma, Ajdacic, Eich, & Rossler, 2008; Neckelmann, Mykletun, & Dahl, 2007; Pigeon et al., 2008). Sleep studies of depressed patients demonstrate that there are key differences in even their sleep architecture (Hall et al., 2000; Kupfer, 1999; Staner et al., 2003). In comparison studies, depressed patients demonstrated longer latency to sleep onset, less sleep efficiency, and more frequent arousals from sleep. From electroencephalography (EEG) studies, depressed patients demonstrated a shift in greater rapid eye movement (REM) sleep toward the earlier portion of the sleep period, and an overall decrease in slow-wave sleep (Kupfer, 1999; Staner et al., 2003). These EEG studies further demonstrate a shift toward heightened nocturnal arousal in depressed patients, which would potentially trigger the development of insomnia symptoms (Staner et al., 2003).

The most alarming factor in the relationship between insomnia and depression is the increased risk for suicide attempt and suicidal ideation. Fawcett et al. (1990) described insomnia as the single most important malleable risk factor for suicide in depressed patients. In a study of suicide attempts in patients with MDD, Agargun and colleagues (2007) found that 100% of participants who had MDD without melancholic symptoms and had attempted suicide also reported having insomnia. Melancholic suicide attempters also reported significantly higher rates of insomnia and sleep disturbance than non-attempters (Agargun et al., 2007). In a study examining depressive symptoms of

people who completed suicide, through post-mortem interview with family and friends, McGirr and colleagues (2007) found insomnia was the most significant symptom related to immediate suicide risk, with a 240% increased risk. There are a few potential explanatory models for this risk, which include the relationship between chronic sleep deprivation and emotional exhaustion, and the shared neurobiological mechanisms (serotonergic and noradrenergic) for insomnia and aggressive behavior (McGirr et al., 2007). Suicide is the worst possible outcome for MDD, and its risk is significantly increased with the presence of insomnia.

Cognitive aspects of MDD may additionally contribute to an increased likelihood of sleep disturbance. For example, a study of dysfunctional beliefs about sleep found that patients with significant depressive symptoms also tended to score highly in dysfunctional beliefs about sleep (Carney, Edinger, Manber, Garson, & Segal, 2007). In particular, participants with MDD tended to catastrophize the effects of having too little sleep, which can significantly increase anxiety related to sleep and then increase the potential for persistent insomnia (Carney et al., 2007).

A National Institutes of Health State-of-the-Science conference was conducted in 2005 concerning the definition of insomnia and the best practice recommendations for its treatment. One of the problems that the conference addressed was the fact that insomnia is often conceptualized as being secondary to a psychological or medical disorder. The conclusion drawn by the panel of experts was that insomnia needs to be conceptualized as a comorbid condition, because the possible etiologic relationships between insomnia and other conditions are often poorly understood and the treatment of insomnia needs to be prioritized. The classification of insomnia as a secondary condition leads to the potential

for under-treatment (NIH, 2005). Furthermore, anti-depressants alone have demonstrated properties for inducing insomnia symptoms (Antai-Ontong, 2004; Winokur, Gary, Rodner, Rae-Red, Fernando, & Szuba, 2001). Anxiety and insomnia have been observed to arise from anti-depressant treatment, and benzodiazepines are often prescribed to address these issues (Kanba, 2004). Unfortunately, the benzodiazepines have an increased risk for dependence and primarily only have efficacy with the treatment of anxiety (Kanba, 2004). In some studies, Cognitive Behavioral Therapy (CBT) demonstrated shortcomings in effectively treating comorbid insomnia and depression (Zayfert & DeViva, 2004), but other studies have demonstrated that CBT was effective in primary and comorbid insomnia (Edinger et al., 2009). There has been some research that demonstrated the combination of CBT for insomnia (CBTI) with pharmacologic treatment for anxiety and depression demonstrated significantly increased efficacy over medication on symptom reduction (Manber et al., 2008; Morin et al., 2009). The treatment models of comorbid insomnia and depression have consistently demonstrated that the conditions respond well to combined treatment.

Stress

Both insomnia and depression models share a key etiology: stress. Stress comes in many shapes, forms, and has a variety of causes. In the simplest terms, stress can be defined as a pattern of responses to events that disturb an individual's equilibrium (Selye, 1991). Ongoing negative social exchanges can be a consistent source of stress, which can come from interpersonal life or from the workplace environment (Newsome, Mahan, Rook, & Krause, 2008). Further, it appears that both reactions to stressors and even appraisal of stress are very individualized. Traditional models of stress indicate that there

are four basic varieties of stress: distress, eustress, hyperstress, and hypostress. Distress indicates the response to events that has a harmful effect. Eustress is viewed as positive stress, because it represents the increased stimulation that comes from positive life events, such as starting a new job or having a baby. Hyperstress is indicative of the situation in which stressful events (positively or negatively valenced) exceed the individual's ability to cope, and hypostress is indicative of the situation in which an individual is understimulated to a degree that they may seek external modes of stimulation (Selye, 1991). Regardless of its causes, stress is strongly related to both physiological and psychological functioning.

Although stress plays a major role in the models of insomnia and depression incidence, it is more likely that the model for both is actually one that is bidirectional. Sleep research throughout the lifespan has demonstrated that sleep disorders in children have been related to stress within the family and the treatment of these sleep disorders results in overall reduction of familial stress levels (Lam, Hiscock & Wake, 2003; Mindell & Durans, 1993). A prospective study of the influence of family life stress and negative life events on insomnia and depression demonstrated that family life stress significantly predicted incidence of insomnia in college students, even when depression levels were controlled in the predictive model (Bernert, Merrill, Braithwaite, Van Orden, & Joiner, 2007). However, their post hoc analyses indicated that insomnia was not a significant predictor of negative life events, indicating that poor sleep was unlikely to result in increased stressors (Bemert et al., 2007).

The workplace is commonly a source of stress for individuals, and has been the focus of many stress reduction studies. There are some indications that the climate of the

American workplace is more stressful than ever, as a result of increased financial volatility, collapse of new businesses, high variability of the stock market, and increased productivity demands in an environment of diminished resources (Lloyd & Foster, 2006). Increased workplace stress levels are associated with poorer diet, less physical activity, increases in smoking, lowered job satisfaction and increased risk for cardiovascular disease (Budden & Sagarin, 2007; Ng & Jeffery, 2003). However, workplace interventions designed to increase employee wellness have demonstrated success at reducing rates of stress-induced illness and increased overall quality of life for American workers (Lloyd & Foster, 2006). Many researchers have demonstrated that workplace wellness programs result in improvement in several key health indicators: weight loss and body fat (Watts & Weigendt, 1992;), physical activity (James, 2001; Shephard, 1989), cholesterol (Watts & Weigendt, 1992), mental health (Butterwoth, Linden, McClay & Leo, 2006), and even increased preventative cancer screenings (Mahaney, 1994).

One area of particular relevance to this study is the study of workplace burnout. Burnout has been described as the multidimensional complaint in which excessive work stress leads to cognitive weariness, emotional exhaustion, and physical fatigue (Melamed, Shirom, Toker, Berliner, & Shapira, 2006). Although burnout is carefully differentiated from anxiety and depression, it shares many similar symptoms, and is associated with clear sleep disturbances (Melamed et al., 2006). Fortunately, burnout also responds to stress reduction interventions, and workplace interventions aimed at improving stress coping significantly reduce the health risks associated with burnout (Melamed et al., 2006).

As workplace wellness programs continue to be expanded and adopted by a wide range of fields, it is important that the programs that are developed adequately address the needs of the working population and also present an attractive option to employees. One of the more attractive and easier to implement wellness programs is the development and adoption of exercise programs within the workforce.

Exercise

Exercise has a unique relationship to the hypothesized primary functions of sleep because it is the stimulus that can elicit the greatest depletion of energy stores, tissue breakdown, and elevation of body temperature (Youngstedt, 2005). Exercise may induce phase shifts in circadian rhythm, in addition to its well documented mood-lifting effects (Leppamaki, Haukka, Lonnqvist, & Partonen, 2004). Exercise is associated with increased total sleep time and slow-wave sleep, which may be a function of increased body temperature (Cheek et al., 2004).

Low levels of physical activity have been found to be related to a five-fold increased risk of developing insomnia in elderly populations as compared to those with high physical activity (Morgan, 2003). Although excessive arousal is believed to be a contributor to insomnia symptom severity, exercise early in the day can be beneficial to the insomnia patient (Zarcone, 2000). A study of Japanese elderly participants found that regular stretching exercises at bedtime resulted in greater subjective sleep quality which in turn improved brain function (Tanaka & Sirakawa, 2004). King, Baumann, O'Sullivan, Wilcox, and Castro (2002) found that moderate intensity exercise, maintained over a twelve-month period, resulted in improved subjective sleep quality and lessened perceived stress in a cohort of post-menopausal familial caregivers. In a study of light

and exercise therapy as a treatment of depression, pre-treatment insomnia was found to be predictive of positive treatment response (Leppamaki, Haukka, Lohnqvist, & Portonen, 2004). Prior trials of exercise as a treatment of sleep disorders have been very limited by their small sample size, tendency to use younger patient populations and a limited scope of exercise treatment, but have been found to significantly decrease mean sleep latency and increase sleep efficiency (Montgomery & Dennis, 2004).

Experiments examining the impact of exercise on clinical depression consistently demonstrate a positive relationship between exercise and symptom alleviation. In a population-based study in the Netherlands, regular physical exercise was significantly negatively associated with anxiety, depression symptoms, and neuroticism (DeMoor, Beem, Stubbe, Boomsma, & DeGeus, 2006). In a review article of the relationship between depression and exercise, Barbour and Blumenthal (2005) found that exercise leads to a reduction in both somatic complaints and depressive symptoms, as compared to social contact. Additionally, exercise was as efficacious in symptom alleviation as pharmacological treatment. Furthermore, there was evidence that participants with depression were consistently able to adhere to an exercise regimen, furthering the case for exercise as an alternative to pharmacotherapy (Barbour & Blumenthal, 2005). In a meta-analysis of exercise treatment interventions, treatment attrition for experimental interventions was 19.9% as compared to 20.7% to 31.4% attrition for differing pharmocotherapies (Stathopoulou, Powers, Berry, Smits, & Otto, 2006). In prior studies, exercise was found to increase quality of life and decrease depressive symptoms (Smith & McFall, 2005). In a study where exercise was compared with pharmacologic (sertraline) treatment for depression, only 8% of the exercise group had relapsed as

compared to 30% of those treated with pharmacotherapy (Barbour & Blumenthal, 2005). Reductions in depressive symptoms have been demonstrated in older populations (over 65 years of age) after either a cardiovascular or a stretching exercise regimen, and these reductions persisted at the five year follow-up (Motl, Konopack, McAuley, Elavsky, Jerome, & Marquez, 2005). Increasing exercise in response to stressors, exercise coping, has been demonstrated to effectively reduce depressive symptoms even in the face of negative life events or medical illness (Harris et al., 2006). In a study of exercise attitudes and work stress, physical exercise ameliorated the effects of work stress (Budden & Sagarin, 2007). However, in another study of work and exercise, people in the most stressful job category, were the least likely to participate in physical exercise (Payne, Jones, & Harris, 2002). Increases in physical self-esteem resulting from completion of a physical exercise regimen are related to long-term reductions in depressive symptoms (Motl et al., 2005). Exercise increases individual sense of ability to achieve desired results (self-efficacy) and decreases tendency to dwell on problems (Craft, 2005).

In clinical experimentation studies with both rats and human adults, exercise was found to reduce cortisol levels associated with stress and depression and resulted in lasting cortical changes demonstrating reversal of biochemical basis for depression (Stathopoulou et al., 2006; Zheng et al., 2006). According to a study of the biochemical changes that occur in relation to exercise intensity, higher intensity cardiovascular exercise was associated with increased release of beta-endorphin, a hormone that acts on dopamine receptors and is associated with improved mood and analgesic effects (Radosevich, Nash, Lacy, O'Donovan, Williams, & Abumrad, 1989). Release of beta-endorphin is an endogenous reward for physical activity, and is associated with the

efficacy of physical exercise at improving mood states (Radosevich et al., 1989; Yeung, 1996). High intensity cardiovascular exercise results in increases in beta-endorphin and corticotrophin releasing hormone, which are directly related to improved mood (Antunes et al., 2005; Harte, Eifert, & Smith, 1995). Most athletes and even novice exercisers experience some degree of increased beta-endorphin release after cardiovascular exercise, with a positive dose-response relationship between exercise intensity and length of exercise period (Oktadalen, Solberg, Haugen, & Opstad, 2001).

There are several features of physical activity interventions that play a critical role in their efficacy. First of all, the length of the session of exercise is significantly associated with its influence on depressive symptoms. Osei-Tutu and Campagna (2005) found that long sessions of exercise (30 minute) resulted in significant mood improvement, as compared to shorter sessions of exercise interspersed through the day. Plante and colleagues (2007) found that women felt most positive about exercise that was performed individually (as opposed to within groups) and outside. Pronk, Crouse, and Boback (1995) found that, among women, there were significant increases in mood following maximal exercise testing (physical fitness testing that pushes the participant to their highest level of cardiovascular fitness). A study of older adults, found that sedentary older adults experienced significant long-term depressive symptom reduction when introduced to either a light cardiovascular exercise regimen or a stretching and strengthening cardiovascular exercise regimen (Motl et al., 2005).

Several studies have demonstrated that differences in exercise modality may be related to mood improvement. In particular, there is some debate as to whether aerobic activity is necessary to induce improvement in mood state (Antunes et al., 2005; Berger

& Owen, 1992; Netz & Lidor, 2003; Oken et al., 2006). There is concern that aerobic exercise is not as attractive to sedentary individuals, and that slower, more relaxation-based activities may be equally as advantageous. In a comparison of a variety of exercise modes, Netz and Lidor (2003) found that both aerobic (swimming) and mindfulness stretching exercises (yoga and Feldenkrais, gentle body stretching) were effective in creating mood improvement immediately following exercise. They concluded that mindfulness stretching, due to the fact that it is less physically exhausting, may be a more effective manner in which physical activity can be utilized for mood improvement in depressed individuals (Netz & Lidor, 2003). In contrast, Oman and King (2000) found that participants were more adherent to a higher intensity physical activity regimen in the face of adverse life events than they were to lower intensity physical activity. It is likely that the intensity of the activity caused greater endorphin release which was reinforcing to the participants, even though both groups had prior histories of physical inactivity (Oman & King, 2000). As further evidence of support for high intensity arobic exercise, Antunes and colleagues (2005) found that high intensity sessions of stationary cycling, led to significant improvement in depressed mood and anxiety.

One of the major barriers to exercise as a treatment for the population targeted by this study is the fact that people experiencing stress, depression and insomnia are very likely to be feeling fatigued, sluggish, and have low self-efficacy toward their ability to exercise. It can be very difficult to motivate depressed individuals to engage in an exercise routine and these individuals have a tendency to blame themselves for any failure of the exercise routine, which decreases the likelihood they will persist with exercise in the face of any challenges (Seime & Vickers, 2006). Furthermore, intentions

to exercise do not always coincide with actual exercise behavior (Budden & Sagarin, 2007; Payne et al., 2002). In an exploration of factors that increase adherence to an exercise program, Seime and Vickers (2006) demonstrated that orientation to the exercise facility and individual contact significantly increased adherence. Perception of increased mood following sessions of exercise also led to greater adherence to physical activity (Berger & Owen, 1992).

Prolonged adherence to physical activity regimens demonstrates lifestyle change, which is the ultimate goal for behavioral treatment. Chronic exercise, as in consistent sessions of exercise for more than twelve weeks, has been found to significantly reduce feelings of fatigue, which motivates and reinforces the behavior (Puetz, O'Conner, & Dishman, 2006). In order for regular physical exercise to become a lasting lifestyle modification, there must be some long-term maintenance of the behavior beyond the intervention itself (Heesch, Masse, Dunn, Frankowski, & Mullen, 2003). The development of a protocol that creates a positive association between exercise and mood will likely work toward the establishment of permanent lifestyle change that may have a significant impact on both symptoms of depression and insomnia. Having the protocol available at the worksite may further decrease participation resistance, since it involves fewer steps on behalf of the participant. It is particularly important, however, that the protocol developed is not simply a workplace exercise intervention, but that it additionally incorporates principles of CBT, because the incorporation of elements of therapy may increase the likelihood that the participants would view the exercise regimen as an opportunity to cope with sleep difficulties, depressed mood, and stress. Rather than

hoping that these coping strategies would develop as a result of participation, presenting the elements of therapy introduce the strategy from the very beginning of participation.

Cognitive Principles

Beck's cognitive theory of depression proposes that there is a predisposition toward depression (diathesis) which is triggered by a stress or series of stressors, which then results in symptoms of depression (Oei, Bullbeck, & Campbell, 2006). Cognitive vulnerability toward depression is evidenced through negative automatic thoughts or schemas (persistent patterns of interpreting information) which increase the tendency to interpret experiences on a negative valence, increasing tendency toward depressed feelings. An individual with a tendency toward depression will interpret stressors as part of a pervasive negative experience, which reaffirms depressed feelings. Depressed mood then changes the manner in which the individual interacts with their environment, which often results in further negative experience and creates behavioral persistence of depressed mood (Oei et al., 2006). For example, an individual experiencing depression may try to attend a social event to bring their mood up, but may turn people off with their depressed affect and poor interpersonal skills, which results in a negative experience for the depressed individual.

According to Hammen's (2006) stress generation theory, depressed individuals can create stressful and negative interpersonal experiences by the manner in which they interact in social situations. These self-generated stressful events can cause depressed feelings to persist, and have even remained when depression itself has remitted (Hammen, 2006). Negative experiences reaffirm the individual's depressed mood and the schema that all experiences will be negative, which can then result in the refusal to

attend any further social events. This theory parallels the predisposing, perpetuating, and persisting factors approach to insomnia, in that the predisposition toward insomnia is activated by a significant period of stress or illness, which alters sleep behaviors and then is persisted through negative thoughts regarding sleep and increased psychological arousal (Benca, 2005). Negative automatic thoughts, maladaptive schema, and behavioral dysregulation are essential factors in the perpetuation of mood disorders, primary insomnia, and comorbid insomnia and mood disorders (Carney et al., 2007).

Cognitive Behavioral Therapy works at dismantling depression through the breakdown of the cognitive factors that support depression. It includes interventions that focus on observable, depressive behaviors, dysfunctional automatic thoughts or cognitive distortions, and underlying schema. The treatment is progressive, with the behaviors addressed initially, followed by the assessment and correction of negative automatic thoughts, and concluding with the identification and modification of depressive schemas (Jacobson et al., 1996). Cognitive therapy primarily works at the immediate reduction of depressive symptoms, while gradually moving toward a reduction in negative automatic thoughts and the dysfunctional attitudes that allow depression to persist. Cognitive interventions target the negative automatic thoughts that comprise the tendency toward negatively valenced emotional experience (Oei et al., 2006b). In both its complete form, and approaches that have utilized components of the treatment, either behavioral analysis and change or negative automatic thought approach, CBT is effective at reducing depressive symptoms immediately following treatment and at six-month follow-up (Jacobson et al., 1996).

In a study analyzing the active components of CBT it was determined that changing negative automatic thoughts was not the primary action resulting in reducing depressive symptoms (Oei et al., 2006). Rather, the positive environmental factors experienced within the CBT treatment group emerged as the primary anti-depressive treatment component (Oei et al., 2006). An additional study that compared patients in CBT treatment who achieved recovery of depressive symptoms with a non-recovered CBT treatment cohort found that mood improvement and increased activity were significantly related with remission of symptoms (Oei & Sullivan, 1999). The activation hypothesis, the idea that the participation in a twelve-week intervention enables the depressed patient to become reinvested in moving toward becoming well, has been one of the essential ideas in explaining the overall efficacy of CBT. A secondary hypothesis for the increased efficacy of CBT as a treatment for depression has been the coping hypothesis, which indicates that the coping skills that are learned in CBT help establish a new method of handling stressors that would have previously resulted in depressive thinking (Jacobson et al., 1996). Both of these hypotheses gained support with the Jacobsen and colleagues study (1996) that demonstrated that behavioral activation and addressing automatic thoughts were as effective as full cognitive therapy in reducing depressive symptomatology.

The EBCT treatment regimen is primarily designed to create positive emotional experience at each session and increase physical activity; as such, it will maximize the critical effective elements of CBT. Brief models of CBT have been tested with insomnia and have demonstrated significant improvements over baseline symptoms (Edinger et al., 2008; Goodie, Isler, Hunter, & Peterson, 2009). Positive emotional experience will result

from increased beta-endorphin release from the intensity of the cardiovascular exercise, while the focus on problems and goals in the midst of the regimen will lead to utilization of exercise as a coping mechanism for psychosocial stress. Physical fitness will be assessed prior to the intervention and immediately following the intervention to identify changes that will likely result from participation. Each session will additionally incorporate a psycho-educational component in which participants will be introduced to the errors in thinking associated with perpetuating depressive feelings, and will be instructed to utilize knowledge of these thinking errors while focusing on identified current stressors. The program will be offered in the workplace to participants who identify themselves as experiencing stress, which will help to reduce resistance toward participation. The introduction of an effective method of dealing with negative thoughts and stressors will enable participants to reframe stressors in their lives as they occur, which will further resemble the cognitive changes that are desired in CBT treatment. A detailed description of the proposed intervention will be provided in the methods section.

Summary

Insomnia and depression represent major health crises in the United States, and new treatment options are needed. Psychological stress is commonly associated with the incidence of both insomnia and depression, and can be a perpetuating factor in their presence. Insomnia and depression are frequently comorbid, and should be treated as unique disorders with a common treatment modality. Although medications has been a primary treatment option, their associated side effects and lack of efficacy indicate that behavioral treatment options may have the greatest long-term treatment potential. Although the predispositions to both disorders are often organic and can even potentially

be genetic in nature, the factors that allow the condition to persist and potentially relapse are predominantly psychological in nature. Negative and maladaptive thought patterns, and poor behavioral regulation are essential factors in the perpetuation of both disorders, and neither of these factors are effectively addressed through pharmaceutical treatment. A model for the predisposing and perpetuating factors for insomnia and depression is presented in Figure 1.

Exercise treatment can result in increased activation and coping which increase treatment efficacy and can be maintained over time. Although many different types of exercise have demonstrated efficacy at improving insomnia and depressive symptoms, cardiovascular exercise has the unique advantage in that it maximizes beta-endorphin release. This increased release of beta endorphin results in immediate mood improvement, and has been demonstrated to effect long-term biochemical changes in the brain for resolution of depressive tendencies (Oktadalen et al., 2001; Radosevich et al., 1989; Yeung, 1996). The utilization of moderate to high intensity cardiovascular exercise in the EBCT intervention increases potential beta-endorphin release, which will maximize positive mood in the midst of participation, and maximizes homeostatic drive to sleep with increased body temperature and tissue damage (Oktadalen et al., 2001; Youngstedt, 2005). The model for the EBCT treatment effects is demonstrated in Figure 2. The EBCT intervention builds on some of the principle features of cognitive treatment, through its focus on immediate mood improvement through increased behavioral activation and training in negative automatic thoughts and maladaptive thinking patterns; combining these cognitive principles with the physiological benefits of physical exercise creating a unique approach to treatment of insomnia and depression.

CHAPTER 2: RESEARCH DESIGN AND METHODS

This is a feasibility study of a unique treatment approach, with the intention of demonstrating safety and acceptance of the experimental treatment. The main focus of this study is the development of an exercise-based intervention for the treatment of comorbid depression and insomnia. Aims of the study include the following: 1) the EBCT treatment program will be able to be performed in a manner that is safe and attractive to participants; 2) participants in the EBCT regimen will experience mood improvement throughout the course of the intervention; 3) the EBCT treatment will produce improved insomnia and depression symptoms, with decreased latency to sleep onset, increased sleep efficiency, improved subjective mood and sleep quality; and 4) the EBCT treatment program will decrease reported negative automatic thoughts and perceived stress and increase coping self-efficacy.

Aims and Hypotheses

Aim 1. *The development of a protocol for the Exercise Based Cognitive Therapy (EBCT) regimen, with demonstrated safety and ability to be performed as designed*. Hypothesis 1A. At least 80% of the participants will demonstrate moderate acceptance of the treatment condition by attending at least 50% of the twelve sessions of the EBCT protocol. Furthermore, acceptance of the treatment regimen will be demonstrated by the participants' responses to the question assessing the likelihood that they would participate in future EBCT sessions; 80% of respondents are expected to provide responses of 8 or

more on a Likert scale of 1 (Not at all) to 10 (Very Likely). In addition, it is expected that 80% of respondents will report that the EBC treatment helped.

Hypothesis1B. There will be no reports of injury as result of participation in the EBCT protocol.

Aim 2. *The experimental treatment regimen will result in improved mood immediately following EBCT sessions, with sessions 1, 5, 9, and 12 selected for assessment.*

Hypothesis 2. Participants will report higher levels of positive affect and lower levels of negative affect post EBCT sessions (1, 5, 9, and 12 selected for assessment) as compared to their pre-session values.

Aim 3. *Participants will evidence reduced depressive symptoms, negative automatic thoughts, perceived stress, and anxiety. In addition, participants will report improved sleep quality, increases in coping self-efficacy, and physical fitness by the end of the intervention period.*

Hypothesis 3A. Post-intervention values for depression will demonstrate improvement over pre-intervention. Furthermore, a decrease in percentage of participants obtaining scores indicating clinical levels of depression is expected. It is likely that the number of sessions attended will affect the amount of improvement in depression (dose response), so that greater attendance will result in greater improvement.

Hypothesis 3B. Participants will demonstrate improved values for insomnia, sleep quality, and actigraphic measures at the end of the intervention period. Post-intervention actigraphy information will demonstrate reduced latency to sleep onset and wake after sleep onset, and increased sleep efficiency and total sleep time as compared to pre-

intervention values. The number of sessions attended is expected to be positively associated with the amount of improvement.

Hypothesis 3C. Participants will demonstrate post-intervention reductions in anxiety, stress and negative automatic thoughts and increases in coping self-efficacy as compared to pre-intervention values. Greater number of sessions attended will be associated with pre-post changes in these outcomes.

Hypothesis 3D. Participants may demonstrate improvement in physical fitness and resting HR post-intervention. The intervention involves physical activity, which may result in increases in physical fitness. As resting HR is often used as an indicator of physical fitness, it would be expected that changes in resting HR and physical fitness would be closely related to each other. Number of sessions attended is expected to be positively associated with changes in these measures.

Participants and Procedures

Participants were recruited through the posting of flyers and e-mails sent to the entire staff at Charlotte Eye, Ear, Nose, and Throat Associates by the principal investigator (PI). The recruitment flyer described the program as a stress reduction program for employees, and is attached as Appendix B. Confirmation of appropriateness to participate in the study regimen was based upon willingness to complete the 6 week intervention, and availability to attend the sessions as offered. The PI discussed with each participant the emphasis the protocol placed on insomnia and depression, and participants were encouraged to consider whether they wanted to be included in a regimen designed to address these conditions. The EBCT treatment regimen involved 18 participants divided into four cohorts. Sessions were performed outside as weather permitted, with the

intention of taking advantage of the natural light exposure and tendency for individuals to have greater enjoyment of outdoor exercise (Plante et al., 2007). A majority of the sessions were performed on an outdoor track (0.10 mile length) within walking distance of the main office; treadmills at an indoor gym were available as needed, but were not utilized. The EBCT sessions were lead by the PI who had received training in group therapy and physical fitness. All research assistants working on the trial were trained by the PI. Since all of the participants worked for the same company, participants were informed in advance that all self disclosure in response to discussion prompts should be limited to their own comfort level. Participants signed a consent that incorporated limitations of the group setting and highlighted the importance of maintaining confidentiality and mutual respect. The consent is provided in Appendix C. Participants were entered into a drawing for $100 for the completion of each portion of the study. Physical characteristics such as height, weight, and resting heart rate (HR) were obtained during the initial screening session. The use of the HR monitor was explained to the participants and HR zones were determined based upon the age-related calculation for 65-85% heart rate maximum (American College of Sports Medicine [ACSM], 2002; Motl et al., 2005). This is a commonly used practice to determine the intensity of exercise relative to improving cardiovascular fitness. Baseline questionnaires were self-administered during a pre-intervention appointment, and each participant received an actigraph to monitor their sleep and was instructed on how to use the equipment. Participants wore the actigraph for two consecutive days after the completion of baseline questionnaires. A more detailed description of the study's measures is provided in the next section.

Inclusion criteria:

- Between the ages of 18 and 65 years
- Willingness to participate in physical activity
- Exercises less than 2 hours per week during the previous 6 months (as defined as purposive exercise participation through pre-screening contact with participant)

Exclusion criteria:

- Pregnancy or breast-feeding
- Uncontrolled symptoms of menopause (i.e., hot flashes)
- A diagnosis of Bipolar Disorder, Schizophrenia or any other psychotic disorder
- Initiation of any psychotropic or insomnia medication during the course of the study period
- Initiation of any herbal or naturopathic treatments for insomnia or mood
- Receiving active treatment for any other sleep disorder (i.e., obstructive sleep apnea, restless legs syndrome) during the course of the study
- The presence of a medical condition (e.g., chronic asthma, knee replacement surgery) that interferes with participants' ability to exercise

Measures

The complete packet of questionnaires is included as Appendix D.

Demographic characteristics. Basic demographic information was collected, including age, race/ethnicity, sex, marital status, and highest level of educational attainment.

Treatment history. All participants were screened for prior and current treatment of insomnia and depression.

Depression and Anxiety Symptoms. The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a 14-item self-report measure developed to screen for anxiety and depression symptoms. The measure consists of two 7-item subscales: a depression and an anxiety subscale. Items are rated on a scale ranging from 0 (not present) to 3 (maximally present). A cut-off score of 8 or more for each of the subscales has been empirically validated as an effective indicator of the presence of anxiety or depressive disorder in accordance with DSM-IV criteria for adults and adolescents (Bjelland, Dahl, Haug, & Neckelmann, 2002; White, Leach, Sims, Atkinson, & Cottrell, 1999). The HADS has been found to be as effective of a measure of depression and anxiety changes as a daily diary study with significantly less effort (Arving, Glimelius, & Brandberg, 2008). A unique feature of the HADS over other existing anxiety and depression measures is the fact that there is no emphasis on physical symptoms that potentially overlap with insomnia symptoms (Neckelmann, Mykletun, & Dahl, 2007). The measure demonstrated good internal reliability; Cronbach's alpha for the anxiety subscale of the study population was 0.84, and for the depression subscale was 0.79.

Affective Experience. Participants in the EBCT study group were assessed for their subjective emotional state prior to selected EBCT sessions (i.e., 1, 5, 9, and 12) and immediately following these sessions with the Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988). The PANAS was developed as a brief scale to detect positive and negative affective valence. It consists of ten positively valenced affective words and ten negatively valenced affective words, with Likert scale ratings ranging from 1 (very slightly or not at all) to 5 (extremely). In its original design, the authors made the time-frame malleable, such that affective rating can be related to

persistent feeling (affective trait) or able to detect changes in affect valence in short periods of time. For this study, the timeframe "at this moment" was used to assess for immediate emotions. The PANAS demonstrated excellent external validity in evaluation studies, and strongly correlated with standard measures of depression, anxiety, and subjective mood state (Watson et al., 1988). The construction of the NA and PA subscales demonstrate discriminant validity with very little correlation between the PA and NA scales, ranging from -0.12 to -0.23 (Watson et al., 1988).

Stress. The Perceived Stress Scale (PSS; Cohen, Karamack, & Mermelstein, 1983) is a 10-item self report scale that measures levels of general stress. Items are rated from 0-3, with a maximum of 30. The scale was developed for use with a broad variety of populations, and allows for the incorporation of any potential source of life stress. There are no cut-off scores for this scale, although greater stress levels are indicated with higher scores (Cohen et al., 1983). Internal reliability for the study population was good (Cronbach's $\alpha = 0.82$).

Insomnia. The most effective manner in which to assess insomnia symptomatology in research is through the combination of information from both empirically-validated self-report measures and objective assessment (Buysee, Acoli-Israel, Edinger, & Morin, 2006), thus the study included subjective assessments of insomnia and actigraphy.

Self-assessment of insomnia. The Insomnia Severity Index (ISI; Morin, 1993) is a short (7-item) scale that assesses insomnia symptoms over the preceding two weeks. This measure was developed to be more sensitive to subjective insomnia complaints than other sleep measures, and has been empirically validated in clinical populations (cancer; Savard, Savard, Simard, & Ivers, 2005; chronic pain, Tang, Wright, & Salkovskis, 2007).

It utilizes a Likert scale with ratings from 0 (none) to 4 (very severe) yielding possible scores of 0 to 28; a cut-off score of 14 indicates clinical detection of primary insomnia (Smith & Trinder, 2001). The ISI has demonstrated adequate internal reliability (Cronbach's α =.78) for the study population.

Sleep Quality. The Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) assesses subjective sleep quality for the preceding one month. The PSQI was designed to assess a variety of sleep disturbances and has demonstrated efficacy for assessment of insomnia symptoms. The scale consists of 10 main items and 10 sub-category items, for a total of 20 scale items. The PSQI provides the following composite scores: Overall Sleep Quality, Sleep Latency, Overall Sleep Time, Sleep Efficiency, Sleep Disruption, Sleep Medications, and Daytime Functioning. In addition, a Global score can be calculated. A Global score above 7 is indicative of significant impairment (Buysse et al., 1989). The PSQI has demonstrated good internal reliability within this study sample (Cronbach's α =.80).

Actigraphy. Actigraphy consists of a small device, approximately the size of a wristwatch, which can be placed on the wrist or ankle at night: a photograph of the device is in Figure 3. The study utilized the GT1M model from The Actigraph, LLC. It recorded gross motor activity, and the information was down-loaded to software that uses algorithms to convert raw data to sleep wake estimates (Spielman et al., 2000). Actigraphy has a 91-93% agreement with polysomnography findings, but is significantly more cost effective (Sadeh, Sharkey, & Carskadon, 1994). Actigraphy has been specifically validated with insomniac populations, and has been found to have concurrent validity with polysomnography for number of awakenings after sleep onset, amount of

wake time after sleep onset, sleep efficiency, and total sleep time (Lichstein et al., 2006). Each actigraph recording was evaluated by the PI to determine latency to sleep onset, wake after sleep onset, total sleep time, and sleep efficiency. Latency to sleep onset above 20 minutes and sleep efficiency less than 85% are considered of clinical concern. The relevance of improvement in sleep parameters was relative to the ability of each participant to reach normal sleep latency and sleep efficiency, but even improvement toward normalcy on these measures may be beneficial to the participants' overall health (Zorick & Walsh, 2000). For example, a participant that started off with a latency to sleep onset of one hour, would likely be relieved by an improvement to 30 minutes, even though less than 20 minutes is the standard for normal sleep latency. Each participant wore the actigraph for two forty-eight hour periods, with the start time being at the completion of the baseline questionnaire, and again at the completion of post-intervention questionnaires. For standardization, the actigraph was placed on the dominant hand or the right hand for individuals who were ambidextrous. Sadeh et al. (1994) found that there was no particular difference in which hand was utilized for actigraphy, but recommended utilizing a standard approach when assessing for sleep quality in experimental conditions. Further, these authors determined that one evening of recording is sufficient, but warned that an additional evening may be beneficial for ruling out potential artifact (Sadeh et al., 1994). Congruent with these recommendations, participant sleep quality was the average for the two nights during which they wore the actigraph. If a participant reported that one night was unusual or unusable in some manner, for example, they had to take a child to the emergency room, only the valid night was used. In order to determine that there has been no artifact in the recorded sleep, all participants were asked to keep a brief sleep log

for the period that was recorded, limited to timing of sleep and noting anything unusual about the sleep environment (e.g., bed partner present, slept in a car, etc.). Any data that were believed to be compromised (i.e., missing data or incongruent data) by artifact were discarded, and only the hours that are determined to be correct (through artifact recognition and participant report) were utilized. Of the 18 participants with baseline data, 13 participants had data in which two nights were used and 5 participants had data in which only one night was used. Of the five participants in which only one night was used, 3 recordings were not usable due to errors in data collection and 2 recording were discarded because the participants stated that the night had been particularly unusual. In the 14 participants with follow-up data, 9 participants had data in which two nights were used, 4 participants had data in which one night was used, and 1 participant did not have data. The participant who did not have data experienced an error in the recording device, as did 2 of the 4 participants in which only one night was usable. The 2 remaining participants reported that one of the recording nights was a very unusual night of sleep.

Coping Self-Efficacy. The Coping *Self-Efficacy Scale* (CSE; Chesney, Neilands, Chambers, Taylor, & Folkman, 2006) is a 26-item self-report scale that assesses an individual's confidence to perform coping behaviors when faced with life's challenges. Higher scores indicate higher self-reported capabilities to cope with problems through coping strategies such as gaining support from friends and family, using problem-focused coping, and stopping unpleasant emotions. The measure has demonstrated good concurrent validity when compared with other existing measures of coping and self-efficacy (Chesney et al., 2006). Cronbach's alpha for the sample was 0.97.

Automatic Negative Thoughts. The Automatic Thoughts Questionnaire (ATQ; Hollon & Keddall, 1980) is a 30-item self report scale that identifies and measures the frequency of occurrence of automatic negative thoughts associated with depression (i.e., tendency toward "all or nothing" thinking patterns, catastrophizing, and "mind reading"). The scale was initially developed with college students, but has been validated as a reliable measure of depressive thought patterns against other standardized measures of depression (Minnesota Multiphasic Personality Inventory, Depression subscale and Beck Depression Inventory) with a Cronbach's alpha coefficient of 0.98 for clinical populations and 0.91 for nondepressed medical patients (Harrell & Ryon, 1983). Internal reliability for the measure in this study was excellent (Cronbach's α =.97).

Physical fitness. The Three-Minute Step Test (3MST; American College of Sports Medicine, 2002) is a protocol for assessing submaximal cardiovascular physical fitness. It accurately predicts aerobic capacity through its estimation of maximal oxygen consumption (VO_2max). The test involves having the participant step up and down from a 16.25 inch step at a set cadence, and then measuring HR at the end of the three minute time period. This test has been validated in a variety of populations, including children and adaptations for the elderly (Hui & Cheung, 2004; Petrella, Koval, Cunningham, & Patterson, 2003). The protocol for the 3MST is included in the questionnaires in Appendix D.

Heart Rate. Heart rate was measured during the physical fitness evaluation (3MST) and throughout the study sessions using a Polar® Heart rate monitor. This particular HR monitor has demonstrated significant accuracy for usage in studies designed to induce HR changes from either physical or mental task challenges (Goodie, Larkin, & Schauss,

2000). Participants were instructed in how to read the monitor, and the HR alerts were set to each participant's age-based HR range.

Qualitative Feedback. Feedback on satisfaction with the intervention was collected in questionnaire form three months after the completion of the protocol. Qualitative feedback was desired further from completion of the protocol to assess whether the protocol had resulted in any persistent behavioral changes. The qualitative feedback questionnaire is included as Appendix E.

Treatment Conditions

As this is a feasibility study, all of the participants were assigned to the treatment condition, which allowed for maximum exposure to the regimen to a minimal number of participants.

The sessions took place in the following format:

- At sessions 1, 5, 9 and 12, each participant completed a brief pre- session measure of mood.
- At the beginning of each session, participants walked as a group and briefly spoke about their current emotional state and any relevant experiences over the preceding week (5 minutes).
- The instructor asked each participant to identify a personal goal for the week, and identify at least one pressing concern that has been troubling the participant (5 minutes). Participants were instructed that they could share the goals or stressors at will, but were also welcome to keep them private.
- The instructor identified and discussed a negative thought pattern that is common in stress, depression and/or insomnia, and requested that participants reflect on

their own approach to problems in respect to the identified negative thought pattern. Per participant request, discussion topics were sent to all participants in an e-mail after the session had occurred. Discussion topics by session number are presented in Appendix A.

- The instructor led the group in a 45 minute interval running exercise regimen based upon the Jeff Galloway Method for beginning runners (Galloway, 2002). At all times, the participants were reminded to push only as hard as they felt prepared to work, with a goal of achieving at least 65% maximum HR.
    - At set intervals, which grew progressively longer with increasing sessions, participants were instructed to run or speed walk in a manner to significantly increase HR, while focusing on either their goal or stressor. The session plan for the twelve sessions is attached as Appendix A.
        - For example, session one consisted of 15 second running intervals separated by 1 minute walking intervals. During the 15 second running intervals, the participants will be instructed to either focus on their identified goal or their stressor. If the stressor was the focus, the participants were additionally instructed to view the stressor in respect to the negative thought pattern that may be causing it to persist.
    - The final five minutes of the exercise period was dedicated to cooling down and stretching, during which the participants were encouraged to discuss any feelings they have in response to the exercise regimen.

  - The sessions were designed in a manual format by which standardization of the regimen was maintained.

- At sessions 1, 5, 9 and 12, each participant completed a brief post session measure of mood.
- The EBCT sessions lasted for one hour and occurred semi-weekly for the 6-week intervention period for a total of 12 sessions.

Attendance was recorded for each session. If a participant was missing from a session, then the PI contacted the participant a maximum of two times by e-mail.

Procedural Process

The study was initiated with the placement of recruiting posters in the break rooms of the offices of Charlotte Eye Ear Nose & Throat Associates, PA. Potential participants were instructed to contact the PI to discuss the protocol.

Pre-participation Assessment: When potential participants arrived for their initial assessment, the aims of the study were discussed and participants interested in continuing were formally consented. Participants then completed the pre-study questionnaire packet. After packet completion, participants were administered the 3MST physical fitness assessment. Following the physical fitness assessment, participants were instructed in using the actigraph and given an actigraph and sleep log. Participants were instructed to return the actigraph in two days, and were notified when the EBCT cohort would start.

EBCT Sessions: Once a sufficient number of participants had enrolled in the study, the EBCT session cohorts were started. Although it was desired to have between 6 and 8 participants in a cohort, the rate of recruitment resulted in smaller cohorts. The cohorts ranged in size between 3 and 7 participants. Attendance was recorded by research staff at

each EBCT session, and the pre-post-session PANAS data were collected immediately preceding and after sessions 1, 5, 9 and 12. If a participant withdrew at any point after starting participation in the EBCT sessions, they were encouraged to complete the follow-up measures.

Follow-up: At the conclusion of the EBCT intervention the study measures (HADS, PSS, ISI, PSQI, CSE, & ATQ) were administered. After completion of the measures, the 3MST physical fitness evaluation was conducted and participants were instructed in the use of the actigraph. Participants were instructed to return the actigraph within two days. Drawing for the $100 cash prize occurred at the end of the four EBCT sessions. Participants completed qualitative feedback questionnaires three months after the completion of the study.

Study Personnel

The study personnel consisted solely of the PI and two undergraduate research assistants. One undergraduate assistant was responsible for training the participants on the use of the actigraph and data collection. Both undergraduate assistants participated in data entry and the EBCT sessions. During the EBCT sessions, the undergraduate assistants instructed participants on utilization of the HR monitors and then encouraged them in achieving their HR goals. All study personnel were under the supervision of the doctoral dissertation committee chair, Dr. Virginia Gil-Rivas.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences software, Version 17 (SPSS, Inc., Chicago, IL).

Plan of Analysis

Exploratory data analyses were performed to determine the distribution of the outcome measures at each time point. Internal reliability estimates (Cronbach's alpha) were obtained for all measures included. Statistical analysis by aim and hypothesis was as follows:

Aim 1/Hypothesis 1A. Descriptive analyses were conducted to assess the percentage of participants who completed at least half of the EBCT sessions and the overall acceptance of the intervention. In addition, qualitative data were examined for response themes to determine participants' acceptance of the intervention.

Aim 1/Hypothesis 1B. Participant injury logs were examined to determine the occurrence of injuries associated with the intervention.

Aim 2/Hypothesis 2. Paired samples t-tests were utilized to determine if participants demonstrated significant changes in affect from pre- to post-selected sessions.

Aim 3/Hypothesis 3A. An Analysis of Covariance (ANCOVA) was conducted to examine pre- to post-intervention changes in depression scores with number of sessions attended included as a covariate.

Aim 3/Hypothesis 3B. Differences in pre- post-intervention sleep questionnaire data (insomnia and sleep quality) were examined using ANCOVA with session attendance utilized as a covariate. Insomnia and sleep quality were analyzed separately because there is little overlap in the symptoms that the questionnaires address. All actigraphy measures were analyzed with separate ANCOVA models with session attendance and pre-intervention levels as covariates.

Aim 3/Hypothesis 3C. Pre- and post- intervention values for anxiety, stress, automatic negative thoughts, and coping self-efficacy were compared with separate ANCOVAs, with number of sessions attended and pre-intervention values used as covariates.

Aim 3/Hypothesis 3D. Post-intervention values for physical fitness and resting heart rate were analyzed using separate ANCOVA models with session attendance and pre-intervention levels used as covariates.

Post Hoc Analysis

Although it was intended that all of the EBCT groups would experience the intervention in the same manner as the other groups, it is possible that groups may differ from each other. Each of the groups was evaluated for differences in pre- and post-intervention levels of depression, anxiety, sleep quality, and stress.

Attrition

It was anticipated that not all subjects who started the program would complete the program. Prior studies of exercise treatment have experienced participant attrition that has varied between 0% and 62% (62% was reported in a wait-list control condition, while 51% was the highest attrition rate for an actual exercise intervention), with a mean attrition rate of 20% (Stathopoulou et al., 2006). For this study, expected attrition was set to 30%, which appeared to be a midpoint between the highest and lowest attrition rates. The frequency of participation (i.e., number of sessions attended) was documented for each participant, which allowed for adjusting for varying degrees of participation in the intervention. This provided a comprehensive assessment of how each participant utilized the intervention activities. Attrition was hoped to be minimized through individual, weekly personal (during the EBCT sessions) or phone contact with the PI in case of

absence. The group format of the EBCT sessions further encouraged attendance, as adherence to exercise protocols is increased through interpersonal connection (Heesch et al., 2003).

Human subjects involvement and characteristics

Prior to the initiation of any study protocols or participant recruitment, approval of the protocol was obtained from both the University of North Carolina at Charlotte Institutional Review Board and the administrative team at Charlotte Eye Ear Nose & Throat Associates, PA. Participation in all activities was voluntary and physical exercise intensity was based upon physical condition of the individual participant. One of the primary goals of this phase one clinical trial was that the intervention was appropriate for all age groups. This addressed one limitation of previous research on the efficacy of exercise treatment for depression or insomnia. However, because this is a feasibility study, it was appropriate to only use participants who did not have any perceived physical barriers to exercise. Special classes of subjects were not involved in this study.

Sources of materials

All participants were assigned a number that was not be associated with any personally identifying information, which was the manner by which they were tracked throughout the study process. The study number was the only identifier for all of the information on the participant. A log of participants' name and study number were kept by the PI in case of a lost or forgotten study number. This log remained confidential and was not accessible by anyone other than the PI. This log remained in a password-protected file in the PI's office computer. All data were coded with assigned participant number, and no names were recorded on any hard copies or electronic data sets.

Data and Safety Monitoring Plan

The PI was the primary officer for the investigation safety monitoring plan. All research assistants on the study had completed training from the University of North Carolina at Charlotte Institutional Review Board upon the standards of treatment of human subjects, and the requirements of privacy and confidentiality. Furthermore, the PI maintained careful oversight of all data handling and participant interactions with study staff. Physical condition of the participants was monitored at the assessment intervals and on an as-needed basis. The PI had semi-weekly contact with the EBCT intervention group, and encouraged the reporting of any potential adverse events. There were no adverse events reported during the study. Referral for additional psychological support or medical examination was available as needed, but was not required at any point in the study.

CHAPTER 3: RESULTS

Sample Characteristics

There were 48 responses to the recruiting announcements that were presented to the 506 practice employees. Of the 48 responses, 2 participants were not eligible because they were direct employees of the PI. From the remaining 46 responses, 19 potential participants were able to attend the sessions at the planned times and locations. One participant withdrew prior to completing initial study measures, so she was not included in any data analysis. Of the remaining 18 participants, three withdrew prior to the completion of the twelve study sessions and did not complete post-participation assessments. All three of the participants who withdrew agreed to have all previously collected data included in the study data set.

Despite recruitment efforts that included e-mail announcements and advertisements in employee areas in the practice, the desired number of participants was not achieved. Among the 48 responses to the advertising efforts, the greatest limitation for participation was the timing and location of the sessions. The practice employs 506 full-time employees who are spread through 14 different locations throughout the greater Charlotte area. There was interest from employees in locations that were more than 30 miles outside of the city limits, but there was not enough interest at specific sites to warrant the formation of groups at the remote sites.

Furthermore, employee work hours varied by departments and job duties, with some employees working shorter work weeks with longer hours per days worked, and

other employees were working a more standard work week. The PI had hoped to be able to perform lunch-time sessions in addition to the pre/post work shift sessions, but could not come up with a consistent time in which employees took a lunch. It is commonplace in the practice to work through the lunch hour and leave earlier in the day, but all employee hours are based upon individual agreement with shift supervisor rather than a standard across offices or even departments.

The private practice was selected for a variety of reasons. First of all, there was an existing relationship between the PI and the practice. Second of all, the practice was willing and interested in helping to develop a treatment regimen that was aimed at anxiety, depression, and sleep. The fact that the study incorporated a physical fitness activity warranted some concern that first aid and medical treatment were available to any study participants. Using a group of employed adults allowed for the expectation that the participants would have access to healthcare as needed. Furthermore, the practice made an automatic electrical defibrillator available to the PI, who was trained in its use, throughout the study.

The downside of using a population of working adults was that recruitment was opened to participants who did not necessarily have the clinical conditions desired in the study. Recruitment information was changed from selecting specifically for insomnia and depression to any employee who would be interested in stress reduction. Changing the recruitment materials allowed employees who did not want to identify as experiencing a sleep or psychological disorder feel open to engaging with the study. This stipulation was placed by the practice prior to study recruitment at the site. Although this opened the participant pool, which was necessary to getting the number of participants that were

recruited, it would be necessary to make certain that participants in future efficacy trials have clinical levels of depression and anxiety.

Four cohorts comprised of 18 participants were led in the EBCT protocol. Groups were developed in response to the advertising, and then placed according to availability for site or time. The group sizes varied from the largest group of 7 participants to the smallest group that included 3 participants. Participants responded to both e-mails and recruitment flyers that advertised a stress reduction program. When they initially contacted the PI, they were informed that the focus of the intervention would be insomnia and depression, and that the intervention would focus on the utilization of exercise in a group format. The mean number of sessions attended was 5.00 (*SD* =3.74). The number of sessions attended ranged from 0 to a maximum of 11 sessions. There were no participants who completed all twelve sessions that were offered; 40% of participants attended 6 or more sessions.

The demographic variables are presented in Table 1. All participants were employed with the medical practice in a full-time capacity, with varying roles within the healthcare setting.

After all four cohorts of the study had completed, participants were asked to complete a questionnaire on their impression of the experience. Fifteen participants completed the entire EBCT protocol and were eligible to complete feedback surveys. Of the 15 eligible participants, one participant was not reachable, so the remaining 14 subjects received questionnaires. Eleven of the 14 questionnaires were returned, with a 78.6% response rate.

Participant Retention

From the 18 consented participants, 83% of the participants completed pre and post intervention assessments and some of the EBCT sessions. The three participants who withdrew cited time and schedule conflicts as their reason for withdrawal. The number of participants fell short of the desired 40 in the study design, despite several recruiting efforts from study staff.

Aim 1. Development of a protocol with demonstrated safety and ability to be performed as designed

Hypothesis 1A. Participants were divided into two categories based upon attendance: low acceptance (less than 50% of sessions completed) and moderate to high acceptance (at least 50% of the sessions completed). Of the 15 participants who completed the intervention, 6 participants completed 6 or more sessions of the protocol, resulting in a 40% rate of acceptance. When including the 18 participants who started the study, the rate of acceptance dropped to 33%.

Qualitative feedback was assessed three months after the completion of the protocol and was evaluated. When asked whether they would be interested in participating in an EBCT stress reduction program again, on a scale of 1 (least likely) to 10 (most likely), seven respondents ranked a 10 for their response, two participants ranked a 9, and two participants ranked a 8, which resulted in 100% of the respondents indicating willingness to complete the intervention. Ten of the eleven respondents (91%) stated that they felt that the sessions had helped them. Seven of the eleven (64%) respondents reported that they had increased their physical activity level after participating in the EBCT sessions.

When prompted as to how they felt the intervention had helped them, responses included an emphasis on the stress reductive properties of the program, and the fact that physical activity served as an effective mean for improving mood. One participant stated, "Lowering worry and stress by the way you think about the stressors helps you to be more relaxed and sleep better." Another participant reported, "I enjoyed learning alternate ways to change how I might think about a situation and how to deal with stress caused by daily challenges. Walking and thinking in a more positive manner can definitely elevate your mood!!" Interestingly, even those participants who reported that they were not currently exercising indicated that they had learned to associate physical activity with mood and sleep improvement.

Another theme among the responses was the preference for the group approach. Several respondents listed the group atmosphere as one of the things that they enjoyed about the program. A couple of the respondents stated that the groups had enabled them to make social connections with colleagues that they might otherwise not have had the chance to meet. Although many of the respondents indicated that they would not change anything about the program as presented, a couple of the respondents indicated that they would enjoy greater flexibility to session timing and location. A couple of the participants also suggested that they would have preferred a greater variety of exercises during the sessions. One participant added that she would have preferred having more time for discussion prior to the start of the exercise sessions. Overall, responders reported that their experience with the EBCT protocol had been positive.

Hypothesis 1B. There were no reports of any injuries made by any participants through the course of the intervention, which supported the hypothesis that the intervention could be performed without exposing participants to injury.

Aim 2. Improvements in pre- and post- session mood

Hypothesis 2. Pre- and post-session mean values for positive and negative affect were calculated for sessions 1, 5, 9, and 12. Paired samples T-tests were then performed and the results are presented in Table 2. There were significant differences in both positive and negative affect following session 1. Interestingly, both positive and negative affect demonstrated increase, which was counter to what had been expected. No significant differences were detected in the later sessions for either positive or negative affect; there were larger mean increases in both positive and negative affect but the differences were not statistically significant. This is due predominantly to the smaller sample sizes in the later sessions.

Aim 3. Reductions in symptoms and improved sleep quality

Hypothesis 3A. Mean pre- and post-intervention values for the variables of interest are presented in Table 3. Prior to the start of the intervention, 27.8% of the participants met the depression clinical cut-off score of 8 or more on the HADS questionnaire. After the conclusion of the intervention, only one participant (6.7%) met the clinical criteria for depression. Crosstabs analysis of the difference approached statistical significance (χ^2 =2.75; p =.10). An Analysis of Covariance (ANCOVA) was conducted to examine pre- and post-intervention changes in depression scores with number of sessions attended and pre-intervention depression scores included as covariates. There were significant improvements in depression scores and pre-

intervention scores were the stronger predictors of post-intervention scores. Contrary to expectations, number of sessions attended did not significantly predict post-intervention scores (see Table 4).

Correlations were performed between the change in depression with changes in anxiety, insomnia severity, and sleep quality to see to what degree these changes were related. Change in depression was significantly correlated only with change in sleep quality, r=.64, p<.01.

Hypothesis 3B. Mean pre- and post-intervention values for insomnia and sleep quality are presented in Table 3. Prior to the start of the intervention, 11.2% of the participants met clinical cut-off criteria for insomnia (score at or above 14 on the ISI) and 71.2% of the participants met clinical criteria for poor sleep quality (score at or above 7 on the PSQI). After the conclusion of the intervention, only 6.7% met clinical cut-off for insomnia and 27.8% of participants met clinical criteria for poor sleep quality. Crosstabs analysis of the change in clinical criteria was not significant for insomnia severity and sleep quality. Differences in pre- and post-intervention sleep questionnaire data (insomnia and sleep quality) were examined using ANCOVA with session attendance included as a covariate. Pre- and post-intervention values for the questionnaires are presented in Table 3. Insomnia and sleep quality were analyzed separately because there is little overlap in symptoms. The results for the analyses for insomnia and sleep quality are presented in Table 4. The results indicate that there were significant changes in insomnia values, but the model for sleep quality was not significant indicating that, adjusting for pre-intervention values, participation in EBCT did not contribute to significant improvements in sleep quality.

Post-intervention actigraphy values were analyzed using separate ANCOVA analyses, with session attendance and pre-intervention levels as covariates. The values for the actigraphy variables are presented in Table 5. The results of the ANCOVA analyses are presented in Table 6. Sleep latency could only be estimated for a portion of the participants, because the estimation of sleep latency required the completion of the sleep diary. Participants were unreliable in the completion and submission of sleep diary information, despite being reminded by study staff. The results suggest that sleep latency, sleep efficiency and total sleep time significantly improved over the course of the intervention, with session attendance playing a significant role in the models for each. There were no significant differences between pre- and post-interventions scores for wake after sleep onset.

Examination of clinical criteria for sleep disruption demonstrated a different pattern of change than was observed in the ANCOVA models of the post-intervention actigraphy values. Prior to the intervention, 35.7% of the participants had a latency to sleep onset greater than 20 minutes, and 27.8% of the participants had sleep efficiencies less than 85%. After the intervention period, only 20% of the participants experienced a latency to sleep onset greater than 20 minutes, but 28.6% of the participants still had sleep efficiencies less than 85%. It is possible that sleep latency was more responsive to the initial intervention, whereas sleep efficiency (occurring over the entire course of the evening) is more complex and slower to respond to intervention. Crosstabs analysis of the change in clinical criteria was not significant for sleep latency or sleep efficiency.

Hypothesis 3C. Pre- and post- intervention values for anxiety, stress, automatic negative thoughts, and coping self-efficacy are presented in Table 3. The post-

intervention values for each of these scales were compared with separate ANCOVAs, with number of sessions attended and pre-intervention values used as covariates. Results for the ANCOVA analyses are presented in Table 7. Anxiety, stress, and automatic negative thoughts demonstrated significant change, but session attendance did not significantly explain differences in pre- and post-intervention scores. Coping self-efficacy demonstrated significant improvement, with greater session attendance making a significant contribution to post-intervention scores.

Hypothesis 3D. Pre- and post-intervention values for physical fitness and resting HR are presented in Table 5. Post-intervention values for physical fitness and resting HR were analyzed using separate ANCOVA analyses, with session attendance and pre-intervention levels used as covariates; these models are presented in Table 8. There was no significant change in the physical fitness variables through the intervention period.

A summary of the overall study results as applied to the aims and methods is presented in Table 9.

Post Hoc Analysis

Although it was intended that all of the EBCT groups would experience the intervention in the same manner, it was possible that groups may differ from each other. Each of the groups was evaluated for differences in pre- and post-intervention levels of depression, anxiety, sleep quality, and stress; no significant difference were detected.

CHAPTER 4: DISCUSSION

This is the first study to examine the combination of principles of cognitive behavioral therapy with physical exercise in a group setting. The primary focus of this feasibility study was demonstration that the EBCT program could be performed as designed without negative effects on the participants. There were no adverse reactions reported by any of the participants. Further, the qualitative results indicated that the study was well-received by the participants; 100% of the respondents indicated that they would be willing to participate in the EBCT program again and 91.9% indicated that they felt the sessions had been beneficial for improving their mood and stress level.

A second manner in which the acceptability of the intervention was demonstrated was through rate of attendance and participant retention. On average, participants attended less than half of the twelve sessions. However, when the groups were stratified as low acceptance (3 or less), moderate acceptance (4-8) or high acceptance (9 or more), there were 7, 6, and 5 participants in the groups, respectively. In addition, the participants who withdrew indicated that they were withdrawing due to time conflicts and no participants reported problems with the protocol as reasons for withdrawal. Furthermore, the overall retention rate (83%) was higher than had been expected in the study design, and was significantly higher than rates reported in similar studies involving physical activity as a main factor (Stathopoulou et al., 2006). However, this retention rate was representative of participants who completed pre- and post-intervention assessments, and was not reflective of actual attendance throughout the protocol.

Contrary to expectation, changes in pre- and post-session negative affect were not significant in sessions beyond the first session, and the number of sessions attended was not a significant factor in the model. This finding implies that the reasoning behind attendance was not directly related to perceived mood improvement, and may have been related to other factors. The study staff tried to encourage increased participation through contacting participants who missed sessions and checking as to why they may have been absent. In most cases, participants who missed sessions after work missed as a result of work obligations or childcare conflicts. Participants who missed morning sessions reported over-sleeping as their primary reason for missing the session. Participants who withdrew from the study reported that the time involved in the sessions was the strongest factor in their inability to attend the sessions. Previous studies have demonstrated that people in higher stress jobs would be most likely to benefit from exercise, and are often the least likely to participate in exercise (Payne et al., 2002).

Although the primary focus of this study was feasibility, it was important to assess whether participants experienced any changes in mood, cognitive factors, and physiologic variables in response to their participation in the EBCT program. Participants experienced significant improvements in insomnia, depression, anxiety, and stress, which demonstrate that the study was effective on the outcomes that it was intended to influence. The fact that session attendance was not a significant covariate in many of these models indicates that there may be more to the participation than simply attending sessions. Participants were drawn to the study for its potential effects on stress, and this was confirmed by the degree to which participants experienced reductions in stress levels through the course of the study. Prior research has demonstrated that exercise and

cognitive therapies have a positive impact on depression, anxiety, and stress (DeMoor et al., 2006; Barbour & Blumenthal, 2005; Budden & Sagarin, 2007, Edinger et al., 2009), and this new treatment modality was able to achieve the same positive results.

Changes in sleep variables presented mixed results, which reflect the fact that sleep was measured from several different perspectives. Change in insomnia severity pre- and post-intervention, as measured by the Insomnia Severity Index which uses a clinical significance cut-off score of 7, was not significant. This might be explained by the fact that, on average, pre-intervention scores were below clinical levels. The ISI may have been an ineffective tool for detecting small changes in this population. In contrast, the Pittsburgh Sleep Quality Index Global score demonstrated significant pre- post-intervention changes. The positive changes in sleep quality were previously found in a 12-month regimen of exercise utilized by King et al. (2002), but these changes were achieved in a shorter time frame. These changes were, however, comparable to the timeframes utilized by studies of CBTI (Edinger et al., 2009).

The analyses of the actigraphy measures demonstrated significant changes in total sleep time, sleep latency, and sleep efficiency. The only actigraphy measure that did not demonstrate significant change was minutes of wake after sleep onset. These results are congruent with findings that an exercise program can increase total sleep time, decrease sleep latency and increase sleep efficiency (Cheek et al., 2004; Montgomery & Dennis, 2004). Further, they are congruent with studies of CBTI and its effects on insomnia (Edinger et al., 2009).

Although there have been several studies that have evaluated combined treatment for insomnia and depression, this is the first study that has examined a treatment modality

that incorporates both cognitive behavioral treatment and a physical exercise regimen. Although health has long been viewed as a component of both physical and mental health, it is not very common to find treatment approaches that address both of these facets simultaneously. The participants in this study experienced a significant reduction in automatic negative thoughts, which is reflective of prior studies demonstrating efficacy of CBT interventions (Oei & Sullivan, 1999). In prior studies, cognitive behavioral treatments alone demonstrated shortcomings in effectively treating comorbid insomnia and depression (Zayfert & DeViva, 2004), but other studies have demonstrated that CBTI was effective in primary and comorbid insomnia (Edinger et al., 2009). The most common treatment for both insomnia and depression is pharmacotherapy, even though there are mixed results to this approach (Antai-Ontong, 2004; Kanba, 2004; Winokur et al., 2001).

Many of the results of this study are comparable with past studies that have examined exercise effects on insomnia and depression. Although there was an expectation that exercise would positively affect insomnia and depression, exercise regimens have never been packaged in a combined treatment with principles of CBT. One of the limitations of relying on an exercise treatment regimen for these disorders is concern that patients will not be adherent to the regimen (Payne et al., 2002). However, Stathopoulou et al. (2006) demonstrated that exercise adherence can actually be better than adherence to pharmacotherapy. Although adherence to the present regimen was less than desired, participants experienced symptom reduction and had positive effects as a result of their participation. Furthermore, the structure of the regimen allows for specific psychological and physical exercise goals and sessions, which differ greatly than a

standard recommendation of "starting an exercise plan," or attending therapy. The regimen as a package may be more attractive as a referral source to physicians because of the fact that it has specific sessions and activity levels, and physicians could trust that their patients would be receiving a structured treatment, possibly to the same degree that some psychiatrists have come to trust CBTI for the treatment of insomnia.

The intensity of the physical exercise had been a concern in the study design. It was possible that the intensity of the physical exercise could lead to increased subject attrition. However, the EBCT session plan incorporated gradual increases in intensity. None of the participants indicated that the physical activity itself was related to their decision not to participate, which implies that the exercise modality was accessible to novice exercisers. In the sessions, participants expressed interest in the fact that they could go at their own pace, and that they could use their body's signals (heart rate) to sense if they were working hard enough. Throughout the sessions, the PI assessed the participants' abilities to achieve the desired heart rate range, and all of the participants demonstrated the ability to identify and maintain the desired range for the periods of increased intensity. It is likely that the utilization of discussions both prior and during the exercise sessions helped the participants to feel motivated to continue with the exercise regimen.

Limitations

There are several limitations to the study protocol. This was a treatment-only study, which did not incorporate a control group; it cannot be determined whether or not the changes in the variables of interest could not have occurred with the passage of time rather than the EBCT protocol participation. Furthermore, control and possibly

alternative treatment conditions could allow for the adjustment that participant expectation may have influenced efficacy of the protocol. It would also be beneficial to examine the length of treatment effects by conducting long-term follow-up assessments.

Based on power estimates, a total of 40 participants would be required to detect moderate to large statistical effects, thus the study was limited in its ability to detect the effects of the intervention. Further, given the small sample size and the characteristics of participants the results may not be generalizable to other populations of working adults. The population of working adults was specifically full-time employees in a healthcare practice, and it may be that there were characteristics of this population that were unique. For example, it is possible that healthcare workers may be more willing to participate in exercise than the general public, although the slow recruitment efforts seem to contradict this expectation. Tvieto and Eriksen (2009) demonstrated that recruiting healthcare workers to an exercise regimen and retaining them in the regimen had been particularly challenging, as their job duties were demanding and their work hours varied.

As previously mentioned, site selection was based upon existing professional relationships and willingness of the practice to allow for recruitment. Furthermore, the PI was concerned that study subjects recruited would have easy access to healthcare should any injuries occur. Opening the study to other groups of recruitment was considered, but it seemed more important at this stage of the study to be focused on a population that was alike in several ways (e.g., work duties, schedules, location), and then incorporate a broader group into the next stage of the study. It would be important to secure funding for future studies so that recruitment can be opened to a broader population.

It may further be essential that employers arrange appropriate schedule adjustments to ensure that participants can attend sessions. Many corporations are interested in the concept of workplace wellness, and often these explorations are tempered by the cost that the wellness activities may place in the current employers. There is a good deal of debate as to the degree to which employee wellness programs are attractive to employees (Eaton, Marx, & Bowie, 2007), which methods are most beneficial (Franklin, Rosenbaum, Carey, & Roizen, 2006; Thompson, Smith, & Bybee, 2005) and which programs are cost effective (Haynes, Dunnagan, & Smith, 1999). Allowing for schedule adjustments would give employees the ability to attend wellness activities, and may further enable their continued adherence to the regimen.

Finally, the group format of the exercise regimen blurs the lines in whether it is the intervention itself or the social atmosphere that facilitated change. Prior studies of exercise interventions (Dunn, Trivedi, Kampert, Clark, & Chambliss, 2005) have worked to control the group atmosphere as group exercise can represent a form of social support. In this study, it was desired to create the collaborative atmosphere of group exercise (and therapy), but it may be important to test the protocol as both an individual intervention and a group intervention to determine whether or not the group approach is the most effective form of delivery. Further qualitative assessment of participants' experiences in either setting could offer insight into the perception of the group and its influence on the experience of the protocol.

Future Directions

The EBCT intervention addressed the interaction between physical and mental health, which is multi-faceted. In the next, larger scale study, the EBCT treatment would

be tested against a control group exercise condition, to see if the intervention is more efficacious than the social aspect of individual exercise groups. As a next step, a large-scale treatment study would be important to compare EBCT with traditional Cognitive Behavioral Therapy, to see if this presentation of cognitive training is as efficacious as the traditional formats of CBT. Any future studies would also incorporate longer-term follow-ups, in order to determine if there are wash-out effects on completion of the protocol. Finally, a long-term goal would be the expansion of the EBCT modality to conditions that would benefit from the addition of exercise and psychotherapy, and that are often co-occurring with insomnia and depression. In particular, diabetes has been identified as commonly co-occurring with depression, and inroads are being made to examine the efficacy of cognitive behavioral therapies with diabetic patients (van Bastelaar, Pouwer, Cuijpers, Twisk, & Snoek, 2008) and patients undergoing cancer treatment (Hopko, Robertson, & Carvalho, 2009). Ideally, EBCT would eventually be evaluated with medically ill patients as an alternative therapy.

An advantage of EBCT is that it can be performed in settings outside of the therapy clinic (e.g. YMCA, local gym, local track) and could potentially (with further evaluation) be led by paraprofessional instructors (i.e., trained athletic coaches or nurses) rather than requiring licensure within the field of psychology or counseling. Other studies have examined the efficacy of utilizing nurses and web-based programs for the dissemination of therapy, and this would be another alternative route (nurses: Houghton & Saxon, 2007, computer: van Bastelaar et al., 2009 and Stuhlmiller & Tolchard, 2009). The EBCT regimen creates a hybrid of physical exercise intervention and therapy, and allows for possible increased accessibility for a wider range of participants. One of the

critiques of CBT is that, although we know that it is effective in treating insomnia, depression and other psychological conditions, it is not widely available and the associated costs and levels of counselor training required limit the accessibility of treatment (Gunter & Whittal, 2010; Stuhlmiller & Tolchard, 2009). A population-based study of depression epidemiology demonstrated that only 57% of depressed people are actively receiving any treatment, and that the elderly and non-white individuals are the least likely to receive adequate care (Ohayon, 2007). Of those receiving treatment, only 25.8% of respondents were receiving treatment from a professional with training in therapy (Ohayon, 2007). The necessity of programs that can be widely disseminated and accessible to a broader patient population is apparent.

Conclusions

The primary goal of this study was to address a comorbid condition with a combined treatment modality. This is the first study of record that combined physical fitness with psychotherapy principles into one complete regimen, and it is hopeful that this could be the beginning of a deeper exploration and understanding of how these two different approaches to mental health can be incorporated. The EBCT intervention is simple enough that it can easily be performed in a variety of potential settings. Furthermore, the treatment manual is straightforward, and the statistical analysis demonstrated that session attendance at all sessions may not be necessary. Exercise is a common prescription for rehabilitation and treatment of existing physical disease, and many diseases have comorbid depression and/or insomnia. The difference between EBCT and a standard exercise prescription is that it presents a structured exercise paradigm that

incorporates the desired psychological changes with exercise, and can be easily led by a professional with some training in both exercise and counseling.

Bouts of exercise have been previously demonstrated to improve mood during the course of the exercise program (Osei-Tutu et al., 2005), but persistent mood changes were not detected in this study. Most studies of the relationship between physical exercise and mood do not control for the length or intensity of exercise, which make it very difficult to fully understand which exercise regimens would be most effective for improving mood in the long-term (DeMoor et al., 2006; Harris et al., 2006). The physical risks of EBCT are not different from the risk of any physical exercise routine, and physical exercise is currently being encouraged by the national government. These risks are worth the benefit of added treatment options for complex disorders.

REFERENCE

Agargun, M.Y., Besiroglu, L., Cilli, A.S., Gulec, M., Aydin, A., Inci, R., & Selvi, Y. (2007). Nightmares, suicide attempts, and melancholic features in patients with unipolar major depression. *Journal of Affective Disorders, 98,* 267-270.

Altena, E., Van Der Werf, Y., Strijers, R.L.M., & Van Someren E.J.W. (2008). Sleep loss affects vigilance: effects of chronic insomnia and sleep therapy. *Journal of Sleep Research, 17,* 335-343.

American College of Sports Medicine (2006). *ACSM's Guidelines for Exercise Testing and Prescription 7th Edition*, Whaley, M.H., Brubaker, P.H., & Otto, R.M. (eds.). Philadelphia, PA: Lippincott Williams & Wilkins.

Andrews, B., Hejdenberg, J., & Wilding, J. (2006). Student anxiety and depression: Comparison of questionnaire and interview assessments. *Journal of Affective Disorders, 95,* 29-34.

Antai-Ontong, D. (2004). Antidepressant-induced insomnia: Treatment options. *Perspectives in Psychiatric Care, 40,* 29-33.

Antunes, S.D., Perri, M.G., Riley, J., Kanasky, W.F., Rodrigue, J.R., Sears, S.F., & Martin, A.D. (2005). Differential predictors of adherence in exercise programs with moderate versus higher levels of intensity and frequency. *Journal of Sport & Exercise Psychology, 27,* 171-187.

Arving, C., Glimelius, B., & Brandberg, Y. (2008). Four weeks of daily assessments of anxiety, depression, and activity compared to a point assessment with the Hospital Anxiety and Depression Scale. *Quality of Life Research, 17,* 95-104.

Barbour, K.A., & Blumenthal, J.A. (2005). Exercise training and depression in older adults. *Neurobiology of Aging, 26S,* S119-S123.

Baune, B.T., Adrian, I., & Jacobi, F. (2007). Medical disorders affect health outcome and general functioning depending on comorbid major depression in the general population. *Journal of Psychosomatic Research, 62,* 109-118.

Bjelland, I., Dahl, A., Haug, T.T., & Neckelmann, D.(2002. The validity of the Hospital Anxiety and Depression Scale: An updated literature review. *Journal of Psychosomatic Research, 52,* 69-77.

Belleville, G. & Morin, C. M. (2008). Hypnotic discontinuation in chronic insomnia: Impact of psychological distress, readiness to change, and self-efficacy. *Health Psychology, 27,* 239-248.

Benca, R.M. (2005). Diagnosis and treatment of chronic insomnia: A review. *Psychiatric Services, 56,* 332-343.

Berger, B.G., & Owen, D.R. (1992). Mood alteration with yoga and swimming: Aerobic exercise may not be necessary. *Perceptual Motor Skills, 75,* 1331-1343.

Bernert, R.A., Merrill, K.A., Braithwaite, S.R., Van Orden, K.A., & Joiner, T.E., Jr. (2007). Family life stress and insomnia symptoms in a prospective evaluation of young adults. *Journal of Family Psychology, 21,* 58-66.

Besiroglu, L., Agargun, M.Y., & Inci, R. (2005). Nightmares and terminal insomnia in depressed patients with and without melancholic features. *Psychiatry Research, 133,* 285-287.

Breslau, N., Roth, T., Rosenthal, L., & Andreski, P. (1996). Sleep disturbance and psychiatric disorders: a longitudinal epidemiological study of young adults. *Biological Psychiatry, 39,* 411-418.

Budden, J.S., & Sagarin, B.J. (2007). Implementation intentions, occupational stress, and the exercise intention-behavior relationship. *Journal of Occupational Health Psychology, 12,* 391-401.

Butterworth, S., Linden, A., McClay, W., & Leo, M.C. (2006). Effect of motivational interviewing-based health coaching on employees' physical and mental health status. *Journal of Occupational Health Psychology, 11,* 358-365.

Buysse, D.J., Ancoli-Israel, S., Edinger, J.D., Lichstein, K.L., & Morin, C.M. (2006). Recommendations for a standard research assessment of insomnia. *Sleep: Journal of Sleep and Sleep Disorders Research, 29,* 1155-1173.

Buysse, D.J., Angst, J., Gamma, A., Ajdacic, V., Eich, D., & Rossler, W. (2008). Prevalence, course, and comorbidity of insomnia and depression in young adults. *Sleep: Journal of Sleep and Sleep Disorders Research, 31,* 473-480.

Carney, C.E., Edinger, J.D., Manber, R., Garson, C., & Segal, Z.V. (2007). Beliefs about sleep in disorders characterized by sleep and mood disturbance. *Journal of Psychosomatic Research, 62,* 179-188.

Cheek, R.E., Shaver, J.L.F., & Lentz, M.J. (2004). Variations in sleep hygiene practices of women with and without insomnia. *Research in Nursing & Health, 27,* 225-236.

Chesney, M.A., Neilands, T.B., Chambers, D.B., Taylor, J.M., & Folkman, S. (2006). A validity and reliability study of the coping self-efficacy scale. *British Journal of Health Psychology, 11,* 421-437.

Cohen, S., Karamack, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Human Behavior, 24,* 385-396.

Craft, L.L. (2005). Exercise and clinical depression: examining two psychological mechanisms. *Psychology of Sport and Exercise, 6,* 151-171.

Cukrowicz, K.C., Otamendi, A., Pinto, J.V., Bernert, R.A., Krakow, B., & Joiner, T.E. (2006). The impact of insomnia and sleep disturbances on depression and suicidality. *Dreaming, 16,* 1-10.

Dalton, E.J., Rotundi, D., Levitan, R.D., Kennedy, S.H., & Brown, G.M. (2000). Use of slow-release melatonin in treatment-resistant depression. *Journal of Psychiatry and Neuroscience, 25(1),* 48-52.

DeGennaro, L., Martina, M., Curcio, G., & Ferrara, M. (2004). The relationship between alexithymia, depression, & sleep complaints. *Psychiatry Research, 128,* 253-258.

DeMoor, M.H.M., Beem, A.L., Stubbe, J.H., Boomsma, D.J., DeGeus, E.J.C. (2006). Regular exercise, anxiety, depression and personality: A population-based study. *Preventative Medicine, 42,* 273-279.

Eaton, D.K., Marx, E., Bowie, S.E. (2007). Faculty and staff health promotion: Results from the school health policies and programs study 2006. *Journal of School Health, 77,* 557-566.

Ebmeier, K. P., Donaghey, C. & Steele, J. D. (2006). Recent developments and current controversies in depression. *Lancet, 367,* 153-167.

Edinger, J.D., Olsen, M.K., Stechuchak, K.M., Means, M.K., Lineberger, M.D., Kirby, A., & Carney, C.E. (2009). Cognitive behavioral therapy for patients with primary insomnia or insomnia associated predominantly with mixed psychiatric disorders: A random clinical trial. *Sleep: Journal of Sleep and Sleep Disorders Research, 32,* 499-510.

Everitt, D.E., Avorn, J., & Baker, M.W. (1990). Clinical decision-making in the evaluation and treatment of insomnia. *The American Journal of Medicine, 89,* 357-362.

Fawcett, J., Scheftner, W.A., Fogg, L., Clark, D.C., Young, M.A., Hedeker, D., & Gibbons, R., (1990). Time-related predictors of suicide in major affective disorder. *American Journal of Psychiatry, 147,* 1189–1194.

Ford, D.E. & Cooper-Patrick, L. (2001). Sleep disturbances and mood disorders: An epidemiologic perspective. *Depression and Anxiety, 14,* 3-6.

Franklin, P.D., Rosenbaum, P.F., Carey, M.P., & Roizen, M.F. (2006). Using sequential e-mail messages to promote health behaviors: Evidence of feasibility and reach in a worksite sample. *Journal of Medical Internet Research, 8*, 25-37.

Galloway, J. (2002). *Galloway's Book on Running, Second Edition,* Bolinas, CA: Shelter Publications.

Goodie, J.L., Isler, W.C., Hunter, C., & Peterson, A.L. (2009). Using behavioral health consultants to treat insomnia in primary care: A clinical case series. *Journal of Clinical Psychology, 65,* 294-304.

Goodie, J.L., Larkin, K.T., & Schauss, S. (2000). Validation of the Polar heart rate monitor for assessing heart rate during physical and mental stress. *Journal of Psychophysiology, 14,* 159-164.

Gunter, R.W., & Whittal, M.L. (2010). Dissemination of cognitive-behavioral treatments for anxiety disorders: Overcoming barriers and improving patient access. *Clinical Psychology Review, 30,* 194-202.

Hall, M., Buysse, D.J., Nowell, P.D., Nofzinger, E.A., Houck, P., Reynolds, C.F., & Kupfer, D.J. (2000). Symptoms of stress and depression as correlates of sleep in primary insomnia. *Psychosomatic Medicine, 62,* 227-230.

Hammen, C. (2006). Stress generation in depression: Reflections on origins, research, and future directions. *Journal of Clinical Psychology, 62,* 1065-1082.

Harrell, T.H., & Ryon, N.B. (1983). Cognitive-behavioral assessment of depression: Clinical validation of the automatic thoughts questionnaire. *Journal of Consulting and Clinical Psychology, 51,* 721-725.

Harris, A. H. S., Cronkite, R., & Moos, R. (2006). Physical activity, exercise coping, and depression in a 10-year cohort study of depressed patients. *Journal of Affective Disorders, 93,* 79-85.

Harte, J. L., Eifert, J. L., & Smith, R. (1995). The effects of running and meditation on beta-endorphin, corticotropin-releasing hormone and cortisol in plasma and on mood. *Biological Psychology, 40,* 251-265.

Hauri, P.J. (2000). Primary Insomnia. In M.H. Kryger, T. Roth, & W.C. Dement (Eds.), *Principles and Practices of Sleep Medicine* (pp. 633-639). Philadelphia, PA: W.B. Saunders Company.

Haynes, G., Dunnagan, T., & Smith, V. (1999). Do employees participating in voluntary health promotion programs incur lower health care costs? *Health Promotion International, 14,* 43-52.

Heesch, K.C., Masse, L.C., Dunn, A.L., Frankowski, R.F., & Mullen, P.D. (2003). Does adherence to a lifestyle physical activity intervention predict changes in physical activity? *Journal of Behavioral Medicine, 26,* 333-348.

Holbrook, A.M., Crowther, R., Lotter, A., Cheng, C., & King, D. (2000). The diagnosis and management of insomnia in clinical practice: A practical evidence-based approach. *Canadian Medical Association Journal, 162,* 216-220.

Hollon, S.D., & Kendall, P.C. (1980). Cognitive self-statements in depression: Development of an automatic thoughts questionnaire. *Cognitive Therapy and Research,* 4, 383-395.

Hollon, S.D., Thase, M.E. & Markowitz, J.C. (2002). Treatment and prevention of depression. *Psychological Science in the Public Interest, 3,* 39-77.

Hopko, D.R., Robertson, S.M.C., & Carvalho, J.P. (2009). Sudden gains in depressed cancer patients treated with behavioral activation therapy. *Behavior Therapy, 40,* 346-356.

Houghton, S. & Saxon, D. (2007). An evaluation of large group CBT psych-education for anxiety disorders delivered in routine practice. *Patient Education and Counseling, 68,* 107-110.

Hui, S.S., & Cheung, P.P. (2004). Comparison of the effects of three stepping cadences on the criterion-related validity of a step test in Chinese children. *Measurement in Physical Education and Exercise Science, 8,* 167-179.

Jacobson, N.S., Dobson, K.S., Truax, P.A., Addis, M.E., Koerner, K., Gollan, J.K., Gortner, E., & Price, S.E. (1996). A component analysis of cognitive-behavioral treatment for depression. *Journal of Consulting and Clinical Psychology, 64,* 295-304.

James, G. (2001). A seven-year follow-up comparing attendees and nonattendees at a statewide, school employee wellness conference. *Journal of School Health, 71,* 127-131.

Jansson-Frojmark, M., & Linton, S.J. (2008). The course of insomnia over one year: a longitudinal study in the general population in Sweden. *Sleep: Journal of Sleep and Sleep Disorders Research, 31,* 881-886.

Jindal, R. D., Buysse, D. J., & Thase, M. E. (2004). Maintenance treatment of insomnia: What can we learn from the depression literature? *American Journal of Psychiatry, 161,* 19-24.

Kanba, S. (2004). Psychopharmacology for the clinician. *Journal of Psychiatry and Neuroscience, 29,* 485.

Katon, W., Lin, E.H.B., & Kroenke, K. (2007). The association of depression and anxiety with medical symptom burden in patients with chronic medical illness. *General Hospital Psychiatry, 29,* 147-155.

Katon, W., Russo, J., Von Korff, M., Lin, E., Simon, G., Bush, T., Ludman, E., & Walker, E. (2002). Long-term effects of a collaborative care intervention in persistently depressed primary care patients. *Journal of General Internal Medicine, 17,* 741-748.

Kessler, R.C., Chiu, W.T., Demler, O., & Walters, E.E. (2005). Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry, 62,* 617-27.

King, A.C., Baumann, K., O'Sullivan, P., Wilcox, S., & Castro, C. (2002). Effects of moderate-intensity exercise on physiological, behavioral, and emotional responses to family caregiving: A randomized controlled trial. *Journal of Gerontology: Medical Sciences, 57A,* M26-M36.

Kivimaki, M., Gunnell, D., Lawlor, D.A., Smith, G.D., Pentti, J., Virtanen, M., Elovaino, M., Klaukka, T., & Vahtera, J. (2007). Social inequalities in antidepressant treatment and mortality: A longitudinal register study. *Psychological Medicine, 37,* 373-382.

Kiviniemi, M.T., Voss-Humke, A.M., & Seifert, A.L. (2007). How do I feel about the behavior? The interplay of affective associations with behaviors and cognitive beliefs as influences on physical activity behavior. *Health Psychology, 26,* 152-158.

Kupfer, D.J. (1999). Pathophysiology and management of insomnia during depression. *Annals of Clinical Psychiatry, 11,* 267-276.

Lam, P., Hiscock, H., & Wake, M. (2003). Outcomes of infant sleep problems: A longitudinal study of sleep, behavior, and maternal well-being. *Pediatrics, 111,* 203-207.

Leppamaki, S., Haukka, J., Lohnqvist, J., & Partonen, T. (2004). Drop-out and mood improvement: A randomized controlled trial with light exposure and physical exercise. *BMC Psychiatry 2004, 4,* Article ID 22. Retreived June 4, 2007 from http://www.biomedcentral.com/1471-244X/4/22.

Leykin, Y., Amsterdam, J.D., DeRubeis, R.J., Gallop, R., Shelton, R.C., & Hollen, S. D. (2007). Progressive resistance to a selective serotonin reuptake inhibitor but not to cognitive therapy in the treatment of major depression. *Journal of Consulting and Clinical Psychology, 75,* 267-276.

Lichstein, K.L., Stone, K.C., Donaldson, J., Soeffing, J.P., Murray, D., Lester, K.W., & Aquillard, R.N. (2006). Actigraphy validation with insomnia. *Sleep: Journal of Sleep and Sleep Disorders Research, 29,* 232-239.

Lin, P., Campbell, D.G., Chaney, E.F., Lin, C., Felker, B.L., & Hedrick, S.C. (2005). The influence of patient preference on depression treatment in primary care. *Annals of Behavioral Medicine, 30,* 164-173.

Lloyd, P.J. & Foster, S.L. (2006). Creating healthy, high-performance workplaces: Strategies from health and sports psychology. *Consulting Psychology Journal: Practice and Research, 58,* 23-39.

Manber, R., Clasey, C., Arnow, B., Markowitz, J.C., Thase, M.E., Rush, A.J., Dowling, F., Koscis, J., Trivedi, M., & Keller, M.B. (2005). Assessing insomnia severity in depression: comparison of depression rating scales and sleep diaries. *Journal of Psychiatric Research, 39,* 481-488.

Manber, R., Edinger, J.D., Gress, J.L., San Pedro-Salcedo, M.G., Kuo, T.F., & Kalista, T. (2008). Cognitive behavioral therapy for insomnia enhances depression outcome in patients with comorbid major depressive disorder and insomnia. *Sleep: Journal of Sleep and Sleep Disorders Research, 31,* 489-496.

Mahaney, F.X. (1994). Workplace breast cancer screening signals shift in corporate culture. *JCNI: Journal of the National Cancer Institute, 86,* 746-8.

McGirr, A., Renaud, J., Seguin, M., Alda, M., Benkelfat, C., Lesage, A., & Turecki, G. (2007). An examination of DSM-IV depressive symptoms and risk for suicide completion in major depressive disorder: A psychological autopsy study. *Journal of Affective Disorders, 97,* 203-209.

Melamed, S., Shirom, A., Toker, S., Berliner, S., & Shapira, I. (2006). Burnout and risk of cardiovascular disease: Evidence, possible causal paths, and promising research directions. *Psychological Bulletin, 1323,* 327-353.

Mindell, J.A., & Durand, V.M. (1993). Treatment of childhood sleep disorders: Generalization across disorders and effects on family members. *Journal of Pediatric Psychology, 18,* 731-750.

Montgomery, P. & Dennis, J. (2004). A systematic review of non-pharmacologic therapies for sleep problems in later life. *Sleep Medicine Reviews, 8,* 47-62.

Morgan, K. (2003). Daytime activity and risk factors for late-life insomnia. *Journal of Sleep Research, 12,* 231-238.

Morin, C.M. (2005). Psychological and behavioral treatments for primary insomnia. In M.H. Kryger, T. Roth, & W.C. Dement (Eds.), *Principles and Practices of Sleep Medicine, Fourth Edition* (pp. 726-738). Philadelphia, PA: W.B. Saunders Company.

Morin, C.M. (1993). *Insomnia: Psychological Assessment and Management.* New York, NY: Guilford Press.

Morin, C.M., & Gramling, S.E. (1989). Sleep patterns and aging: Comparison of older adults with and without insomnia complaints. *Psychology and Aging, 4,* 290-294.

Morin, C.M., Vallieres, A., Guay, B., Ivers, H., Savard, J., Merette, C., Bastien, C., & Baillargeon, L. (2009). Cognitive behavioral therapy, singly and combined with medication for persistent insomnia: A randomized controlled trial. *JAMA, 301,* 2005-2015.

Motl, R.W., Konopack, J.F., McAuley, E., Elavsky, S., Jerome, G.J., & Marquez, D.X. (2005). Depressive symptoms among older adults: Long-term reduction after a physical activity intervention. *Journal of Behavioral Medicine, 28,* 385-394.

National Institutes of Health. (2005). State-of-the-Science Conference statement on manifestations and management of chronic insomnia in adults. *NIH Consensus Science Statements, 22,* 1–30. Retrieved January 15, 2008 from http://consensus.nih.gov/2005/insomniastatement.pdf.

Neckelmann, D., Mykletun, A., & Dahl, A.A. (2007). Chronic insomnia as a risk factor for developing anxiety and depression. *Sleep: Journal of Sleep and Sleep Disorders Research , 30,* 873-880.

Netz, Y. & Lidor, R. (2003). Mood alterations in mindful versus aerobic exercise modes. *The Journal of Psychology, 137,* 405-419.

Newsome, J.T., Mahan, T.L., Rook, K.S., & Krause, N. (2008). Stable negative social exchanges and health. *Health Psychology, 27,* 78-86.

Ng, D. M., & Jeffery, R.W. (2003). Relationship between perceived stress and health behaviors in a sample of working adults. *Health Psychology, 22,* 638-642.

Oei, T.P.S., & Browne, A. (2006a). Components of group processes: Have they contributed to the outcome of mood and anxiety disorder patients in a group cognitive-behaviour therapy program? *American Journal of Psychotherapy, 60,* 53-70.

Oei, T.P.S., Bullbeck, K., & Campbell, J.M. (2006b). Cognitive change process during group cognitive behaviour therapy for depression. *Journal of Affective Disorders, 92,* 231-241.

Oei, T.P.S. & Sullivan, L.M. (1999). Cognitive changes following recovery from depression in a group cognitive-behaviour therapy program. *Australian and New Zealand Journal of Psychiatry, 33,* 407-415.

Ohayon, M.M. (2007). Epidemiology of depression and its treatment in the general population. *Journal of Psychiatric Research, 41,* 207-213.

Oken, B.S., Zajdel, D., Kishiyama, S., Flegal, K., Dehen, C., Haas, M., Kraemer, D.F., Lawrence, J., & Leyva, J. (2006). Randomized, controlled, six-month trial of yoga in healthy seniors: Effects on cognition and quality of life. *Alternative Therapies in Health and Medicine, 12,* 40-47.

Oktadalen, O., Solberg, E.E., Haugen, A.H., & Opstad, P.K. (2001). The influence of physical and mental training on plasma beta-endorphin level and pain perception after intensive physical exercise. *Stress and Health, 17,* 121-127.

Oman, R.F. & King, A.C. (2000). The effect of life events and exercise program format on the adoption and maintenance of exercise behavior. *Health Psychology, 19,* 605-612.

Osei-Tutu, K.B. & Compagna, P.D. (2005). The effects of short- vs. long-session exercise on mood, VO2max., and percent body fat. *Preventive Medicine, 40,* 92-98.

Payne, N., Jones, F., & Harris, P. (2002). The impact of working life on health behavior: The effect of job strain on the cognitive predictors of exercise. *Journal of Occupational Health Psychology, 7,* 342-353.

Perlis, M.L., Giles, D.E., Buysse, D.J., Tu,X., & Kupfer, D.J. (1997). Which depressive symptoms are related to which sleep electroencephalographic variables? *Biological Psychiatry, 42,* 904-913.

Petrella, R.J., Koval, J.J., Cunningham, D.A., Paterson, D.H. (2003). Can primary care doctors prescribe exercise to improve fitness? The step test exercise prescription (STEP) project. *American Journal of Preventative Medicine, 24*, 316-322.

Pierce, D. & Gunn, J. (2007). GP's use of problem solving therapy for depression: A qualitative study of barriers to and enablers of evidence based care. *BMC Family Practice, 8,* available at http://www.biomedcentral.com/1471-2296/8/24.

Pigeon, W.R., Hegel, M., Unutzer, J., Fan, M., Sateia, M.J., Lyness, J.M., Phillips, C., & Perlis, M.L. (2008). Is insomnia a perpetuating factor for late-life depression in the IMPACT cohort? *Sleep: Journal of Sleep and Sleep Disorders Research, 31,* 4 81-488.

Plante, T.G., Gores, C., Brecht, C., Carrow, J., Imbs, A., & Willemsen, E. (2007). Does exercise environment enhance the psychological benefits of exercise for women? *International Journal of Stress Management, 14,* 88-98.

Pronk, N.P., Crouse, S.F., & Rohack, J.J. (1995). Maximal exercise and acute mood response in women. *Physiology & Behavior, 57,* 1-4.

Puetz, T.W., O'Conner, P.J., & Dishman, R.K. (2006). Effects of chronic exercise on feelings of energy and fatigue: A quantitative synthesis. *Psychological Bulletin, 132,* 866-876.

Radosevich, P.M., Nash, J.A., Lacy, D.B., O'Donovan, C., Williams, P.E., & Abumrad, N.N. (1989). Effects of low-and high-intensity exercise on plasma and cerebrospinal fluid levels of ir-□-endorphin, ACTH, cortisol, norepinephrine and glucose in the conscious dog. *Brain Research, 498,* 89-98.

Riemann, D. & Voderholzer, U. (2003). Primary insomnia: a risk factor to develop depression? *Journal of Affective Disorders, 76,* 255-259.

Sadeh, A., Sharkey, K.M., & Carskadon (1994). Activity-based sleep-wake identification: An empirical test of methodological issues. *Sleep: Journal of Sleep and Sleep Disorders Research, 17,* 201-207.

Savard, M., Savard, J., & Simard, S. (2005). Empirical validation of the Insomnia Severity Index in cancer patients. *Psycho-Oncology, 14,* 429-441.

Seime, R.J. & Vickers, K.S. (2006). The challenges of treating depression with exercise: From evidence to practice. *Clinical Psychology: Science and Practice, 13(2),* 194-197.

Selye, H. (1991). History and present states of the stress concept. In A. Monat & R.S. Lazarus (Eds.), *Stress and coping: An anthology, Third Edition* (pp.21-34), New York: Columbia University Press.

Shephard, Roy J. (1989). Exercise and employee-wellness initiatives. *Health Education Research, 4,* 233-243.

Smith, M.T., Huang, M.I., & Manber, R. (2005). Cognitive behavior therapy for chronic insomnia occurring within the context of medical and psychiatric disorders. *Clinical Psychology Review, 25,* 559-592.

Smith, D.W. & McFall, S.L. (2005). The relationship of diet and exercise for weight control and the quality of life gap associated with diabetes. *Journal of Psychosomatic Research, 59,* 385-392.

Smith, S., & Trinder, J. (2001).Detecting insomnia: Comparison of four self-report measures of sleep in a young adult population. *Journal of Sleep Research, 10,* 229–235.

Spielman, A.J., Yang, C., & Glovinsky, P.B. (2000). Assessment techniques for insomnia. In M.H. Kryger, T. Roth, & W.C. Dement (Eds.), *Principles and Practices of Sleep Medicine* (pp. 647-656). Philadelphia, PA: W.B. Saunders Company.

Stathopoulou, G., Powers, M.B., Berry, A.C., Smits, J.A., & Otto, M.W. (2006). Exercise interventions for mental health: A quantitative and qualitative review. *Clinical Psychology in Practice, 13,* 179-193.

Stepanski, E.J. & Wyatt, J.K. (2003). Use of sleep hygiene in the treatment of insomnia. *Sleep Medicine Reviews, 7,* 215-225.

Staner, L., Cornette, F., Maurice, D., Viardot, G., Le Bon, O., Haba, J., Staner, C et al.(2003) Sleep microstructure around sleep onset differentiates major depressive insomnia from primary insomnia. *Journal of Sleep Research, 12,* 319-330.

Stuhlmiller, C. & Tolchard, B.(2009). Computer-assisted CBT for depression and anxiety: Increasing accessibility to evidence-based mental health treatment. *Journal of Psychosocial Nursing and Mental Health Services, 47,* 32-39.

Tanaka, H., & Shirakawa, S. (2004). Sleep health, lifestyle and mental health in the Japanese elderly ensuring sleep to promote a healthy brain and mind. *Journal of Psychosomatic Research, 56,* 465-477.

Tang, N.K.Y., Wright, K.J., & Salkovskis, P.M. (2007). Prevalence and correlates of clinical insomnia co-occurring with chronic back pain. *Journal of Sleep Research, 16,* 85-95.

Thompson, S.E., Smith, B.A., Bybee, R.F. (2005). Factors influencing participation in worksite wellness programs among minority and underserved populations. *Family & Community Health, 28,* 267-273.

Tveito, T.H., & Eriksen, H.R. (2009) Integrated health programme: A workplace randomized controlled trial. *Journal of Advanced Nursing, 65*, 110–119.

van Bastelaar, K.M.P., Pouwer, F., Cuijpers, P., Twisk, J.W.R., & Snoek, F.J.(2008). Web-based cognitive behavioral therapy (W-CBT) for diabetes patients with co-morbid depression: Design of a randomized controlled trial. *BMC Psychiatry, 8,* Article ID 9. Retrieved May 24, 2010 from http://www.biomedcentral.com/1471-244X/8/9

Wang, M., Wang, S., & Tsai, P. (2005). Cognitive behavioural therapy for primary insomnia: a systematic review. *Journal of Advanced Nursing, 50(5),* 553-564.

Watson, D., Clark, L.A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: The PANAS scales. *Journal of Personality and Social Psychology, 54,* 1063-1070.

Watts, P. R., & Waigandt, A. (1992). A university employee wellness program follow-up study and its implications. *Wellness Perspectives, 9,* 14-24.

White, D., Leach, C., Sims, R., Atkinson, M., & Cottrell, D. (1999). Validation of the Hospital Anxiety and Depression Scale for use with adolescents. *British Journal of Psychiatry, 175,* 452-454.

Winokur, A., Gary, K.A., Rodner, S., Rae-Red, C., Fernando, A.T., & Szuba, M.P. (2001). Depression, sleep physiology, and antidepressant drugs. *Depression and Anxiety, 14,* 19-28.

Yeung, R.R. (1996). The acute effects of exercise on mood state. *Journal of Psychosomatic Research, 40,* 123-141.

Youngstedt, S.D. (2005). Effects of exercise on sleep. *Clinical Sports Medicine, 24,* 355-365.

Zarcone, V.P. (2000). Sleep hygiene. In M.H. Kryger, T. Roth, & W.C. Dement (Eds.), *Principles and Practices of Sleep Medicine* (pp. 657-662). Philadelphia, PA: W.B. Saunders Company.

Zavesicka, L., Brunovsky, M., Matousek, M., & Sos, P. (2008). Discontinuation of hypnotics during cognitive behavioural therapy for insomnia. *BMC Psychiatry, 8,* Article ID 80. Retrieved February 1, 2009, from http://www.biomedcentral.com /1471-244X/8/80.

Zayfert, C. & DeViva, J.C. (2004). Residual insomnia following cognitive behavioral therapy for PTSD. *Journal of Traumatic Stress, 17,* 69-73.

Ziwi, R., Shawe-Taylor, M., & Murray, J. (2005). Cognitive processes in the maintenance of insomnia and co-morbid anxiety. *Behavioural and Cognitive Psychotherapy, 33,* 333-342.

Zheng, H. Liu, Y., Li, W., Yanga, B., Chena, D., Wang, X., Jiang, Z., Wang, H., Wang, Z. Cornelisson, G., & Halberg, F. (2006). Beneficial effects of exercise and its molecular mechanisms on depression in rats. *Behavioural Brain Research, 168*, 47–55.

Zigmond, A.S., & Snaith, R.P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica, 67,* 361-370.

Zorick, F.J., & Walsh, J.K. (2000). Evaluation and management of insomnia: An overview. In M.H. Kryger, T. Roth, & W.C. Dement (Eds.), *Principles and Practices of Sleep Medicine* (pp. 615-624). Philadelphia, PA: W.B. Saunders Company.

TABLES

Table 1

Demographic Characteristics

Variable	*%*
Female	100.0
Race	
Caucasian	72.2
African American	27.8
Education	
High School/Some college	44.4
Bachelor's Degree	44.4
Post-graduate education	11.1
Marital Status	
Single	16.7
Married	61.1
Divorced	22.2
Age	*M* = 38.9 (*SD* =9.0)

Note. *N* = 18

Table 2

Pre- and Post-intervention Affect Scores

Session (n)	Positive Affect		Negative Affect	
	Pre	Post	Pre	Post
	M (SD)	M (SD)	M (SD)	M (SD)
1 (15)	27.20 (2.91)	28.07 (3.08)**	24.33 (2.23)	24.40 (3.09)*
5 (5)	27.20 (4.66)	29.40 (2.79)	24.60 (6.84)	24.00 (1.58)
9 (5)	24.20 (4.82)	29.20 (5.67)	21.00 (5.61)	22.80 (2.77)
12 (3)	20.67 (0.58)	24.67 (6.11)	17.33 (2.31)	20.67 (5.13)

* $p < .05$; ** $p < .01$ for paired samples t-test.

Table 3

Descriptive Statistics for Key Variables of Interest

Variable	*Pre-Treatment* *M* (SD)	*Post-Treatment* M (SD)
Depression	6.73 (3.52)	3.07 (2.43)**
Anxiety	9.47 (3.96)	6.67 (3.02)**
Insomnia Severity Index	9.33 (4.51)	6.60 (4.01)*
Pittsburgh Sleep Quality Index		
Overall Sleep Quality	1.60(0.91)	0.93(0.80)**
Sleep Latency	0.93(1.10)	0.53(0.64)
Overall Sleep Time	1.47(0.74)	0.80(0.68)**
Sleep Efficiency	0.87(0.99)	0.47(0.92)
Sleep Disruption	1.53(0.64)	1.20(0.56)*
Sleep Medications	1.13(0.74)	1.07(1.03)
Daytime Functioning	1.00 (0.93)	0.73 (0.59)
Global	8.53 (3.54)	5.73 (3.20)**
Automatic Thoughts Questionnaire	67.07 (24.71)	51.47(21.58)**
Coping Self Efficacy	135.33(46.52)	169.27(33.21)**
Perceived Stress Scale	24.93(2.76)	17.07(4.40)**

Note. Pre-treatment, N=18; post-treatment, N=15; * $p < .05$; ** $p < .01$ for paired samples t-test

Table 4

ANCOVA Model for Questionnaire Variables Depression, Insomnia, and Sleep Quality

	df	F	η^2
Depression			
Corrected Model	2	12.34**	.67
Intercept	1	0.99	.08
Sessions	1	3.38	.22
Pre-Intervention Depression	1	13.94**	.54
Insomnia			
Corrected Model	2	5.90*	.50
Intercept	1	1.39	.10
Sessions	1	1.37	.10
Pre-Intervention Insomnia	1	9.93**	.45
Sleep Quality			
Corrected Model	2	3.70	.38
Intercept	1	0.85	.07
Sessions	1	0.55	.04
Pre-Intervention Sleep Quality	1	6.77*	.36

Note. $N = 15$. * $p < .05$; ** $p < .01$

Table 5

Descriptive Statistics for Actigraphy and Physical Fitness

Variable	Pre-Treatment Mean M (SD)	Post-Treatment M (SD)
Sleep Latency	8.89 (9.94)	9.33 (11.70)
Wake After Sleep Onset	56.57 (39.75)	54.82 (37.20)
Sleep Efficiency	86.16 (8.56)	87.93 (7.64)
Overall Sleep Time	430.11 (79.95)	457.57 (69.83)
Physical Fitness (VO_2max)	41.86 (3.62)	42.62 (3.54)
Resting Heart Rate	87.00 (14.69)	79.67 (10.70)*
Exercise Minutes (weekly)	25.00 (58.43)	103.89 (67.57)**

Note. Pre-treatment, N=18; post-treatment, N=15; * $p < .05$; ** $p < .01$ for paired samples t-test

Table 6

ANCOVA Models for Actigraphy Variables

	df	F	η^2
Sleep Latency			
Corrected Model	2	5.59*	.65
Intercept	1	6.42*	.52
Sessions	1	6.53*	.52
Pre-Intervention Sleep Latency	1	7.69*	.56
Wake After Sleep Onset			
Corrected Model	2	4.08	.48
Intercept	1	9.14*	.50
Sessions	1	4.54	.34
Pre-Intervention Wake After Sleep Onset	1	0.77	.08
Total Sleep Time (TST)			
Corrected Model	2	4.68*	.51
Intercept	1	4.56	.34
Sessions	1	5.69*	.39
Pre-Intervention Total Sleep Time	1	4.61	.34
Sleep Efficiency			
Corrected Model	2	8.19**	.65
Intercept	1	8.14*	.48
Sessions	1	7.38*	.45
Pre-Intervention Sleep Efficiency	1	5.07	.36

Note. N = 14, except for sleep latency where N=9. * $p < .05$; ** $p < .01$

Table 7

ANCOVA Model for Other Variables of Interest

	df	F	η^2
Anxiety			
Corrected Model	2	21.82**	.78
Intercept	1	0.09	.01
Sessions	1	3.75	.12
Pre-Intervention Anxiety	1	40.81**	.77
Perceived Stress			
Corrected Model	2	4.46*	.43
Intercept	1	0.24	.02
Sessions	1	0.79	.06
Pre-Intervention Stress	1	6.75*	.36
Automatic Negative Thoughts			
Corrected Model	2	14.12**	.70
Intercept	1	1.81	.13
Sessions	1	2.04	.15
Pre-Intervention ANT	1	15.24**	.56
Coping Self-Efficacy			
Corrected Model	2	12.51**	.68
Intercept	1	30.84**	.72
Sessions	1	11.42**	.49
Pre-Intervention Coping SE	1	6.35*	.35

Note. $N = 15$. * $p < .05$; ** $p < .01$

Table 8

ANCOVA Model for Physical Fitness Variables

	df	F	η^2
VO_2Max			
Corrected Model	2	2.71	.31
Intercept	1	4.03	.25
Sessions	1	0.00	.00
Pre-Intervention VO_2Max	1	5.33*	.31
Resting Heart Rate			
Corrected Model	2	2.36	.28
Intercept	1	10.10**	.46
Sessions	1	0.34	.03
Pre-Intervention Resting HR	1	0.18	.14

Note. $N = 15$. * $p < .05$; ** $p < .01$

Table 9
Study Aims, Hypotheses and Outcomes

Aim	Hypothesis	Assessment Tool (s)	Outcome
1. *The development of a protocol for the Exercise Based Cognitive Therapy (EBCT) regimen, with demonstrated safety and ability to be performed as designed*.	1A. 80% of participants will attend at least 50% of the twelve sessions.; 80% of respondents are expected to provide positive responses on qualitative questionnaire.	Attendance at the EBCT sessions Qualitative data	1A. Partially supported: rate of acceptance for all participants was 33%. 100% of participants expressed willingness to repeat protocol and 91% reported the sessions helped.
	1B. No reports of injury.	Reports of negative outcomes	1B. Supported.
2. *The experimental treatment regimen will result in improved mood immediately following EBCT sessions, with sessions 1, 5, 9, and 12 selected for assessment.*	2. Participants will report higher levels of positive affect and lower levels of negative affect post selected EBCT sessions.	*Positive and Negative Affect Schedule*, pre/post session at selected sessions	Not supported. For session 1, both positive and negative affect demonstrated increase. For later sessions, there were larger mean increases in both positive and negative affect but the differences were not statistically significant.
3. *Participants will evidence reduced depressive symptoms, negative automatic thoughts, perceived stress, and anxiety. In addition, participants will report improved*	3A. Post-intervention values for depression will demonstrate improvement over pre-intervention.	*Hospital Anxiety and Depression Scale (HADS)*	Supported. Rate of clinical depression in participants was reduced from 27.8% to 6.7%; ANCOVA model demonstrated significant improvements.

sleep quality, increases in coping self-efficacy, and physical fitness by the end of the intervention period.	3B. Demonstrate improved values for insomnia, sleep quality, and actigraphic measures at the end of the intervention period.	*Insomnia Severity Index (ISI)* *Pittsburgh Sleep Quality Index (PSQI)* Actigraphy	Partially supported. Reduction on ISI clinical criteria from 11.2% to 6.7% and reduction on PSQI from 71.2% to 27.8%; ANCOVA model for ISI was significant, but PSQI was not. Reduction in clinically significant latency to sleep onset from 35.7% to 20%; ANCOVA analyses demonstrated that sleep latency, sleep efficiency and total sleep time significantly improved over the course of the intervention, with session attendance playing a significant role in the models for each.
	3C. Demonstrate post-intervention reductions in anxiety, stress and negative automatic thoughts and increases in coping self-efficacy as compared to pre-intervention values.	*Hospital Anxiety and Depression Scale (HADS)* *Perceived Stress Scale (PSS)* *Coping Self-Efficacy Scale* *Automatic Thoughts Questionnaire*	Partially supported. Anxiety, stress, and automatic negative thoughts demonstrated significant change, but session attendance was not significant. Coping self-efficacy demonstrated significant

			improvement, session attendance significant in the model.
	3D. Demonstrate improvement in physical fitness and resting HR post-intervention.	Resting Heart Rate 3-minute Step Test	Not supported.

FIGURES

Figure 1: Model for Comorbid Insomnia and Depression

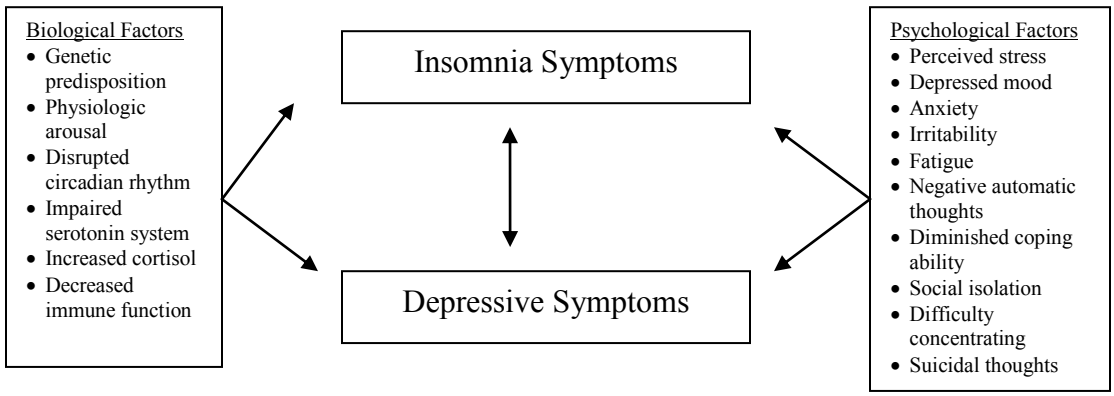


Figure 2: EBCT Treatment Model

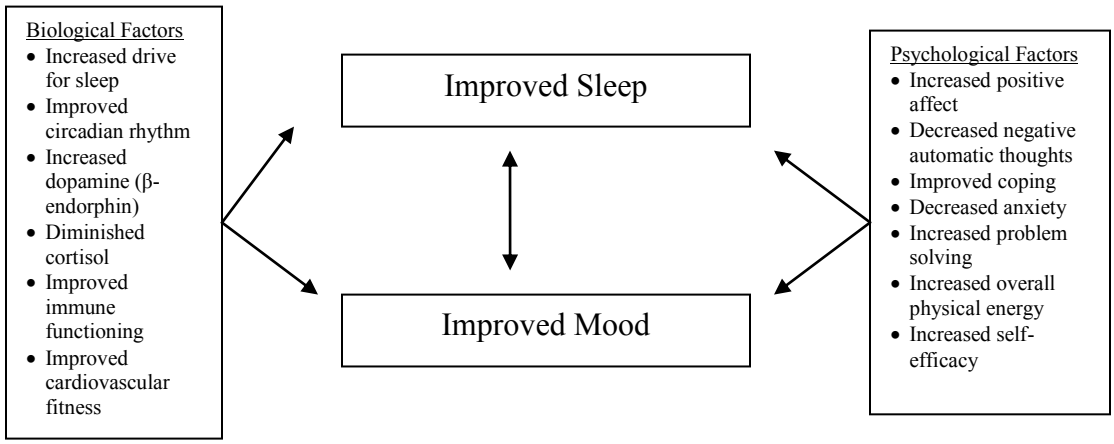


Figure 3. Photograph of actigraph device

Figure 4: Flow Chart of Participation

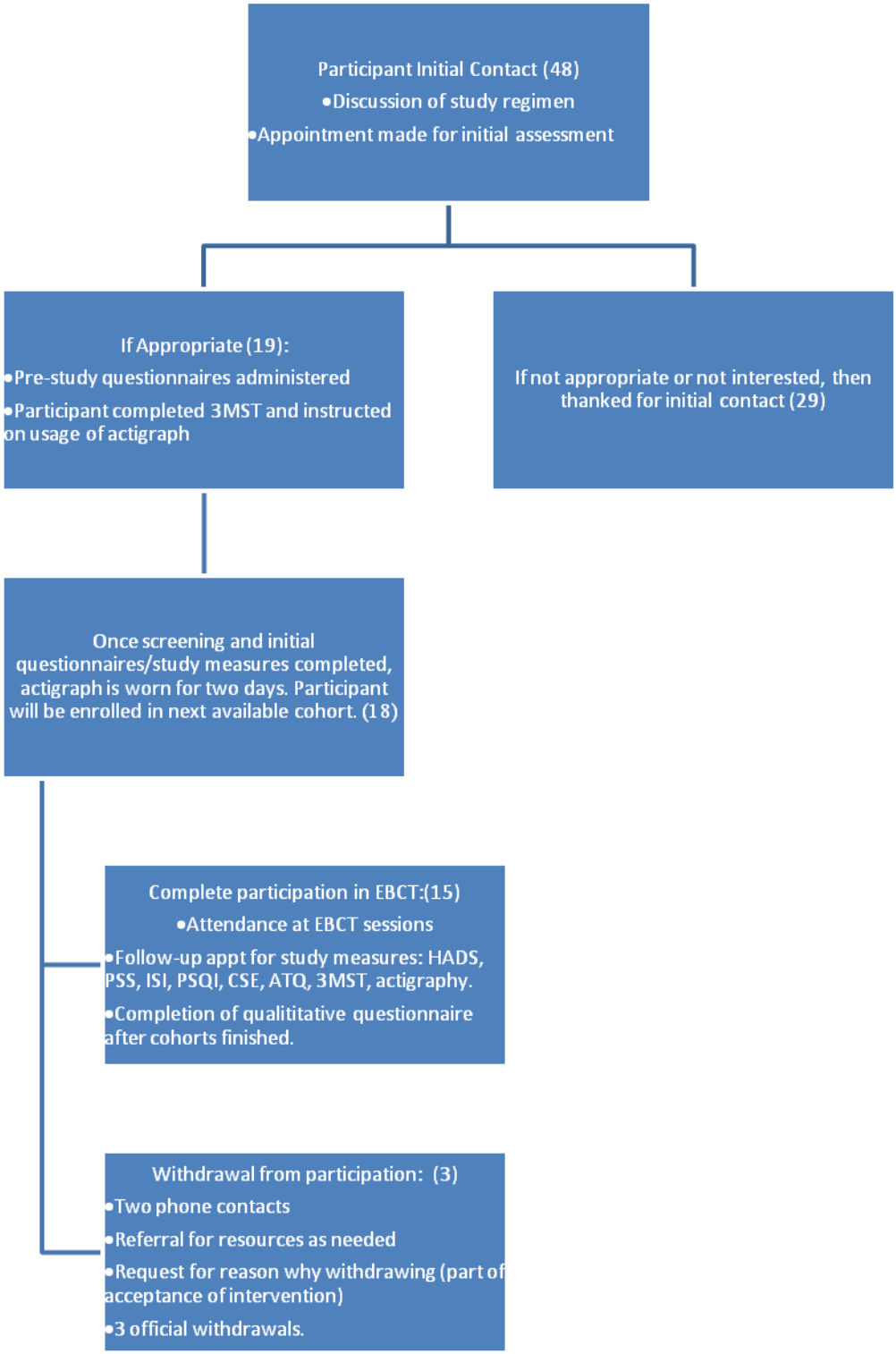
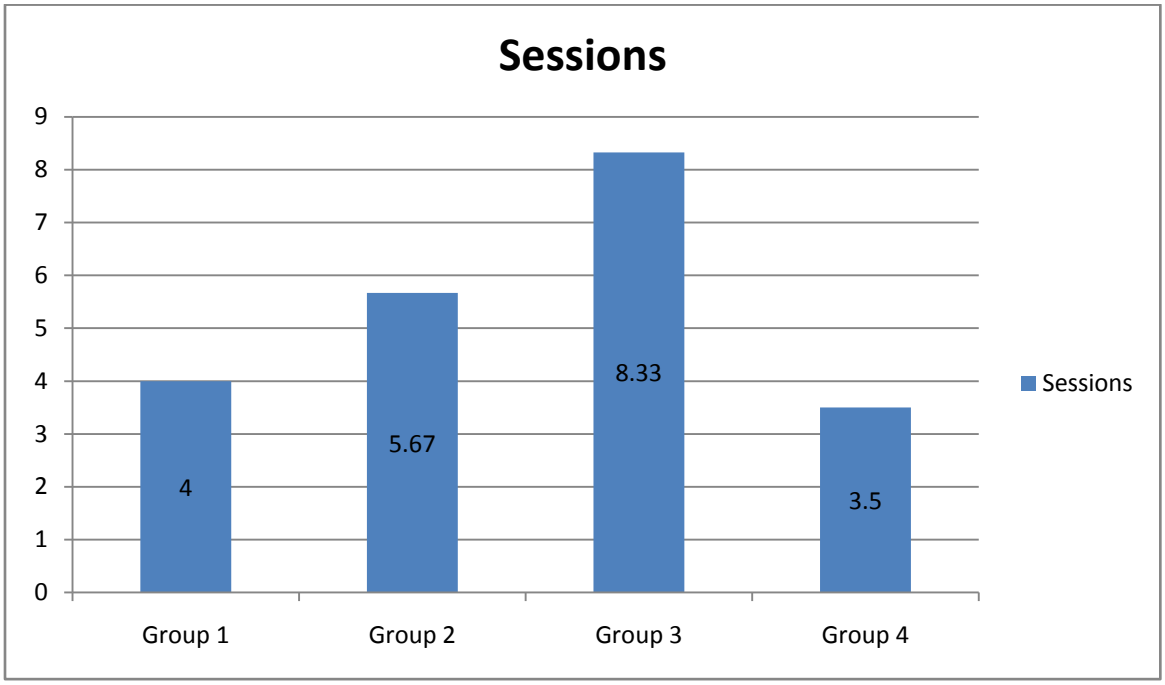


Figure 5: Group Mean Session Attendance



APPENDIX A:

EBCT Session plan

All participants will be encouraged to run or speed walk during the running intervals to try to achieve 70% age predicted heart rate maximum.

Session 1: 15 second running interval/ 1 minute walking interval

Discussion

All or Nothing Thinking

This negative automatic thought occurs when you decide that not succeeding 100% on a task equates a total failure. Emphasis is placed on the aspects of the task that went wrong, rather than the portions that had been quite successful. Although it may seem that focusing on failures may lead to future success; this focus is much more likely to result in depressed mood and feelings of failure.

One of the best things that we can learn is to be gracious and gentle with ourselves. Often, we have high standards for ourselves, and these are reflected in the pressure that we put on everything that we do. Unfortunately, this added pressure is counter-productive. It increases our blood pressure, stress hormones, baseline pulse, and feelings of failure.

As you go through your week, try to recognize situations in which you utilize all or nothing thinking, and instead try to focus on the successes.

Session 2: 15 second running interval/ 1 minute walking interval

Discussion

Anticipating negative outcomes

This negative automatic thought occurs when you think mostly about how badly a future situation may go, rather than allowing events to occur without placing emotional weight on them. This is sometimes called "anticipatory stress," because it is stress created in the preparation for an event, rather than stress caused by an event in the moment.

Interestingly, people often feel that they are preparing themselves for "the worst" or possibly preventing a negative outcome from occurring by placing focus on the worst case scenarios. The thought is that you have prepared for the worst, so will be prepared for anything. This may be adaptive if you are preparing for a trek into the wilderness, but it is destructive in day to day activities. The pattern becomes reinforced when the

experience is not as bad as you have anticipated, so therefore your stress prior to the event "saved" you from the worst case scenario.

As you go through the day, try to recognize any time that you are anticipating a negative outcome, and allow yourself to be hopeful about the event, or even neutral. Recognize where you use this thought pattern, and try to come up with ways to counter it.

Session 3: 30 second running interval/ 1 minute walking interval

Discussion

Discounting the positive

This negative automatic thought occurs when you find yourself focusing on the negative elements of an experience, and completely setting aside the positive. Really stressed out people will decide that positive attributes to their life (e.g. caring friends or a house that you love) are irrelevant and do not outweigh the negative. No matter how tough of a time you are having, there usually are several positives that can make you smile, if you just think about them.

Discounting the positive can also happen in specific situations. I find that some of my employees that really are under a lot of stress will only focus on negative feedback that I give them, even though I always work to give both positive and negative feedback. The thinking is that the negative is where you need to improve, so should be the object of focus. Instead, the positives are the part that you do well, and deserve recognition!

As you go through the next few days, I want you to try to take an inventory of all of the positives that exist in your life. Try to focus on them when you find you are under stress, and try to see if you cannot come up with at least one thought or memory that can make you smile.

Session 4: 30 second running interval/ 1 minute walking interval

Discussion: Emotional Reasoning

This negative automatic thought occurs when you place a larger emphasis on emotions to the extent that you can overlook facts. We are taught at various times that we need to trust our gut, but often our interpretation of an event can be strongly skewed by our emotional state.

For example, a situation can seem even more dire and negative than it actually is, because of the fact that you are emotionally reacting. When we get sad or angry, our blood pressure goes up, and even non-threatening encounters can seem to be threatening. If you had an argument with your supervisor, and then had a less than positive patient

encounter, you would be likely to over-react to the patient problem because you were already negatively "primed."

If you find yourself worrying about an experience, try to step back, and concentrate on the facts of the case. Try to identify when you are weighting your emotional reactions over the facts, and work at placing emphasis toward known facts.

Session 5: 45 second running interval/ 1 minute walking interval

Discussion: Labeling

This negative automatic thought occurs when you use labels to identify experiences, some of which can make situations more stressful than they would be without the label. For example, the label "work" can make a task seem even more stressful because it is related to something you see as stressful.

In addition to labeling, it is also possible to mislabel in ways that make you more depressed or anxious. If I slip on my diet, and think to myself that I am a "loser or "fat pig," I have just made a bad mood worse by the label I chose for the action.

A way to work at this is to pay attention to the way you label behaviors/situations, and try to only use labels that work at making you feel better. Over the next two days, try to focus on labels that you may use, and try to work at keeping them in a way that is the least stressful.

Session 6: 45 second running interval/ 1 minute walking interval

Discussion: Negative Filter

This negative automatic thought relates to the manner in which you interpret the world around you. People who tend to be depressed or anxious often see the world through a negative filter; focusing almost exclusively on the negatives and seldom noticing the positives. Your sadness or worry can be further justified by all of the additional negatives you see in the world around you, and even within your own relationships.

People who have a negative filter will experience thoughts such as "Look at all of the people at work who dislike me" or "I never succeed when I really try my best at work."

For a simple mood boost, try focusing ONLY on the positives in your life for a day or two. If you are really struggling, it may take some work to come up with positives, but you can do it if you try! Decide that you will put all negatives on the shelf, and live life feeling as good as possible. Play up the relationships with the people who really enjoy your company, and allow yourself some distance from people in your life who may be

overly critical. Adjust your filter, and you will likely find you are feeling much more positive.

Session 7: 1 minute running interval/ 1 minute walking interval

Discussion: Mind Reading

This negative automatic thought is created as a way to reduce social anxiety and tension. People become nervous in social and work situations because they are worried about what people around them are thinking, and are trying to anticipate what will happen through their interactions. You can assume that you know what people think without having sufficient evidence of their thoughts.

When faced with a new social situation, we will try to reduce our anxiety over the situation by trying to predict what others may be thinking. However, our mind reading is usually more related to our mood and how we are feeling than how others react to us. When you are in a sad/bad mood and meet a new colleague, you may think to yourself "He thinks I'm a loser". Another common one that women tend to fall victim to is "They think I am not a great person because I don't dress like they do."

Try to concentrate on how you may be reading minds, and notice if your thoughts are more related to your mood. Do you really feel that you know what people are thinking or are you substituting your own thoughts?

Take a few deep breaths, relax, and decide to make your best impression.

Session 8: 1 minute running interval/ 1 minute walking interval

Discussion: Over-generalization

This negative automatic thought occurs when you perceive a global pattern of negatives on the basis of a single incident. Rather than taking each experience as they come, you decide that one bad experience is predictive that all experiences will be negative. "This generally happens to me. I seem to fail at a lot of things."

An extreme case of this can be found in people who are suffering from depression, and feel that their negative experiences are consistent across all situations and will never alleviate. "This is going to be a bad month, because I have already had a rough couple of days." Anytime that something does not work out, then the generalization is confirmed.

For the next several days, try noticing if you tend to over-generalize. Tell yourself that you would like to live in the moment, and take each day as a new day that can bring almost anything to you.

Session 9: 1 minute running/ 45 second walking interval

Discussion: Should and Must Statements

This discussion really captures the manner in which we can be overly hard on ourselves. Basically, there are three perspectives of the self: the ideal self (what we view as the human ideal), the actual self (who we are when we are brutally honest with ourselves), and the ought self (who we believe we should be). Most depression, anxiety, and stress comes from the differences that we see between our actual self and the ought self. We have no expectation that we would achieve our ideal self, but we feel we should have become our ought self.

The difference between our actual self and ought self is summarized by should or must statements. For example, "I must make the correct food choices when I am on a diet" or "a good mother should do crafts with their children." The statements express the difference perceived between who we are and who we think we should be, and we use these statements as a way to beat ourselves up.
Over the next couple of days, try to identify what your ought self looks like, and how you use should or must statements to try to reinforce your idea that you fall short of the expectation. How can you think differently about yourself? Is it helpful to remind yourself of what your shortcomings are? What kind of statements would best replace the ought statements?

Session 10: 1 minute running/ 45 second walking interval

Discussion: Maladaptive Thoughts

Maladaptive thoughts are thoughts that occur, and usually are accurate, but the focus on them results in increased distress. It is not the thought that is distorted, but your constant attention to the thought. For example, it is a fact that I am overweight, and have the thought "I need to lower my weight." This thought is helpful, when I remind myself of the goal to lose weight when offered cake. It becomes maladaptive when I focus on it to the extent that I become distressed, depressed, and hopeless that it will not change.

The best way to deal with these thoughts is to acknowledge their function, and pay close attention to the extent to which you may use them to punish yourself. If the focus goes outside of usefulness, then it has become maladaptive. For example, I had an employee who made a mistake. She was still upset about the mistake and fixated on it beyond the process of resolving the mistake. At this point, the thought has become maladaptive. We walked through the fact that she needed to tell herself that her focus no longer has any function. With that acknowledgement, you can release the thought.

Try to recognize times that you use thoughts to punish yourself, and let yourself know that this excessive focus will only cause distress.

Session 11: 1 minute running/ 30 second walking interval

Discussion: Misperception

We have a tendency to believe that our interpretation of events is the most accurate one, even though we tend to be very biased by our emotions and prior experiences. The closer we are to a situation, the more emotionally involved we are, which means that we are at greater risk of having a misperception of an event or interchange.

For example, it is very easy to take criticism of your work as a complete slight on your performance as an employee. While criticism is often intended to help you move to a desired performance, people often get so discouraged by it that their performance suffers even more. We can twist even positive statements into perceived criticism or as a source of stress, depending upon how we read into our feelings about the person who is speaking.

When you find yourself wrapped up into an interchange with a situation or a relationship that is very important to you, try to take a step back and think about how you may misperceive or create sources of stress. Use someone who is not involved in the situation as a sounding board, and try to recognize how your emotions color your perception.

Session 12: 1 minute running/ 30 second walking interval

Discussion: Misperception

All through the last 11 sessions, we have discussed a variety of ways in which our perception can be inaccurate. We can skew things toward the negative by focusing on negatives, discounting positives, and trying to interpret events that have not yet happened. The sum of these lessons is that our perception is often strongly influenced by our emotions and prior experiences, which makes it difficult to be accurate.

The perceptions of those around us are also colored by their experience and emotional involvement. Two people can go through the exact same experience, and walk away with a completely different story of what happened. For example, I could give the same feedback to two different employees, and they will likely both walk away with different impressions of what happened.

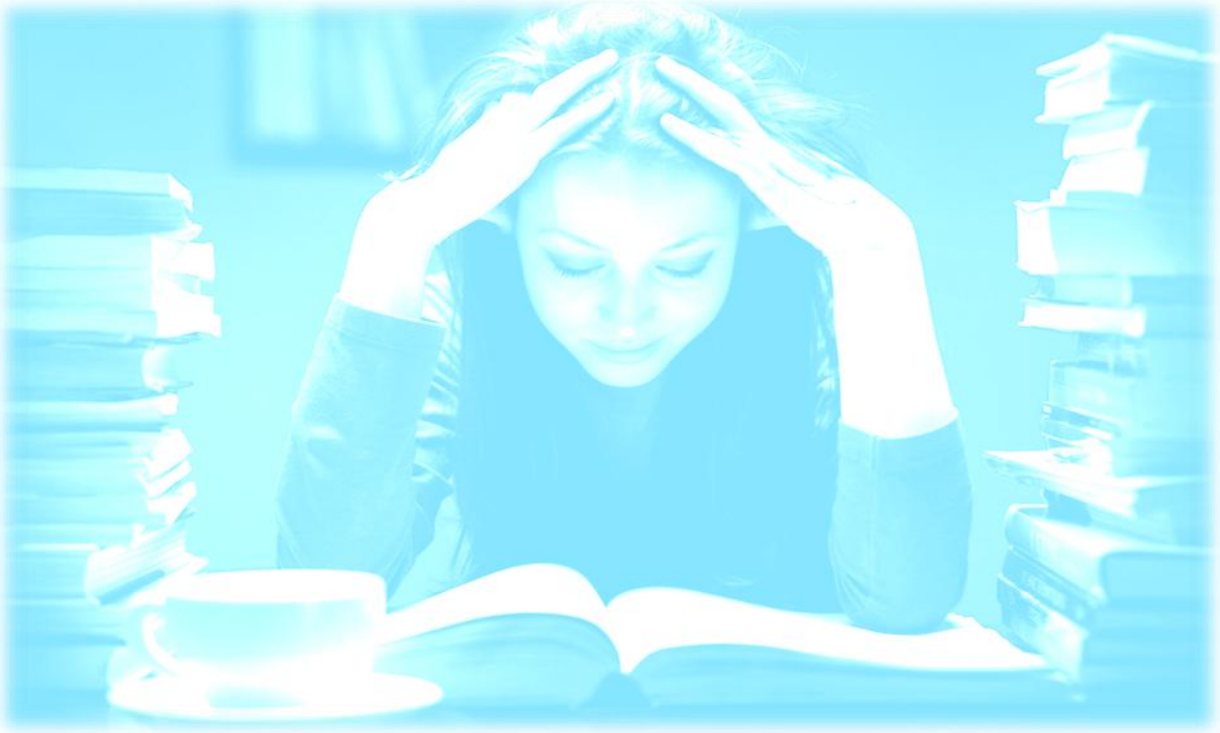
Pay attention to your interpretations, and understand that reality is likely a compromise between your perception and the perception of the other person (people) in the situation. Try not to let your negative automatic thoughts perpetuate stress or low mood, and recognize them as they occur.

APPENDIX B:

EBCT Recruitment Flyer

Is work stressing you out??

Come learn about a new way to cope with stress!



Who: For anyone dealing with stress
What: Exercise-Based Cognitive Therapy
This new treatment trial is being conducted to see if Exercise –Based Cognitive Therapy can help reduce stress levels for individuals dealing with high levels of stress. It is made up of a series of twelve sessions that will take place twice a week for approximately one hour each over a six week period.
*** To learn more about this new treatment trial, please contact the Exercise-Based Cognitive Therapy (EBCT) Research Principal Investigator, Kristin Daley at kdaley@ceenta.com

APPENDIX C: Informed Consent

College of Liberal Arts & Sciences

Department of Psychology

9201 University City Blvd, Charlotte, NC 28223-0001
t/ 704.687.4731 f/ 704.687.3096

Informed Consent for
Exercise-based Cognitive Therapy Feasibility Study

What is the purpose of this study?
The goal of this study is to test a new treatment approach to stress, sleep and depressed mood. Exercise-based cognitive therapy incoprorates physical exercise with cognitive therapy principles with the intent of improving mood and sleep quality.

Who are the researchers working on this project?
The principal investigator is Kristin L. Daley, MA, doctoral student in Health Psychology at the University of North Carolina at Charlotte Institute. Ms. Daley is also Director of Sleep Treatment for Charlotte Eye Ear Nose & Throat Assoc., PA (CEENTA). This project encompasses her doctoral dissertation project. The research is being monitored by her doctoral dissertation committee and the co-principal investigator, Dr. Virginia Gil-Rivas, Assistant Professor of Psychology. Interviews and study sessions will be led by the principal investigator, K. Daley, and her student assistants. This protocol has received approval from the research division of CEENTA, Southeast Clinical Research Associates.

What are the eligibility criteria for participation in this project?
You may participate in this project if you are between 20 and 65 years of age. You must be willing and able to participate in physical activity, and currently exercise less than two hours per week.

What does participation entail and for what period of time?
Approximately 60 people will be participating in this study. Study participation will involve an eight-week time period. Prior to being in the study, you will be asked to complete a survey which will take approximately 45 minutes to complete. The survey will cover health, mood, sleep symptoms, physical fitness, and coping. There will be a physical fitness assessment which will include height, weight, and blood pressure assessment. In addition, you will be in a training session on the use of a personal assistance (PDA), digital pedometer, and an actigraph; this session will last approximately 45 minutes. You will use the PDA during the study period to enter information at different times in the day. All of these entries will be very brief, lasting less than five minutes each. You will be asked to wear the actigraph for 48 hours prior to participating in the study and for 48 hours after the completion of the study. The actigraph is a small, watch-sized device that you will wear on your wrist. It is unobtrusive and does not require any input from you. You will receive a training session for using the actigraph and PDA immediately following the second interview session; this session is expected to last approximately one hour. At the end of

the EBCT sessions, you will be asked to complete a follow-up survey; this survey will take approximately 45 minutes to complete. Finally, you will be asked to continue to wear the pedometer provided by Charlotte Eye Ear Nose & Throat Assoc and your weekly steps will be recorded from your pedometer at the first EBCT session each week.

The study period involves two one-hour sessions per week for six weeks. Participation in the study session will involve a brief group discussion in which you may be asked to report your current mood and any stressors you may be experiencing. You will then be led in a 40 minute running/walking interval class, designed to challenge your physical fitness. The intensity of the workout session will be completely under your control, and you will be instructed in how to adjust the workout to accommodate your fitness level. Assignment to each group will be done on a random basis.

What are the risks and benefits of participating in this study?
There are potential benefits for you from participation in the study. First of all, this intervention has been designed to improve sleep and depressed mood and reduce stress, so it is possible that you may see improvements in your sleep quality, mood and stress level. Furthermore, the intervention may potentially improve your level of cardiovascular fitness, and create a greater interest in exercise. There also may be societal benefits from your participation, as the intervention is being tested as a possible new treatment for psychological and sleep disorders.

The greatest potential risk of participation is the risk of heart attack as a result of extreme exertion during the exercise program. At a lesser level, muscle strain is a risk of participation in any physical activity. These risks will be addressed through preventative education and monitored through instruction by the certified fitness instructor. Furthermore, there is a possibility that the mood questionnaires may arouse negative emotions or depressive symptoms. Your safety will be monitored by the principal investigator, who has five years of graduate training in clinical psychology and clinical training in first aid and cardioplumonary resuscitation (CPR).

Will I be paid for my participation?
All participants will be entered into a drawing for a $100 cash prize at the completion of the intervention period. You will receive one lottery ticket for each interview and each study session attended.

Volunteer Statement
You are a volunteer. The decision to participate in this study is completely up to you. If you decide to be in the study, you may stop at any time. You will not be treated any differently if you decide not to participate in the study or if you stop once you have started. We further request that you treat all of your fellow participants with respect. If there is any problem with behavior or treatment of fellow participants, then you will asked to leave the study. You will still be eligible to participate in the drawing based upon the number of earned tickets.

Is my participation confidential or anonymous?
Any information about your participation, including your identity, is completely confidential. The following steps will be taken to ensure this confidentiality: (a) overall group results will be reported, (b) no personally identifying information will be attached to study data; rather a unique identifier will be assigned to you; (c) background and demographic information obtained will not include your name, and (d) the researchers will follow standard procedures to secure project data (e.g., signed informed consent documents maintained in locked filing cabinets at the research facility, etc.). The limit to your confidentiality exists only in disclosure of information that may be related to harm of yourself or others, of which by law is mandatory. Furthermore, because

participation may involve personal disclosure, all participants are asked at the time of consent to keep personal information confidential. The group sessions will occur in an outdoor setting, but every attempt will be made to ensure that discussions occur in a confidential manner.

What are my responsibilities as a participant?
A major part of your participation will involve a group therapy format. One of the primary principles of group therapy involves an atmosphere of mutual respect and confidentiality. By agreeing to participate in the intervention, and signing this consent form, you are agreeing to maintain an environment of mutual respect and confidentiality with all participants. No problems or situations discussed in the group should be shared with anyone, and you are not to acknowledge group members unless they acknowledge you first. Communication outside of group sessions about this study and your participation in it is discouraged. Any questions about these guidelines should be addressed with the principal investigator.

You will be issued a personal data assistant (PDA) and an actigraph device during your participation. Both of these devices are UNCC property and need to be treated with the utmost respect. Upon your receipt of either device, you will sign an agreement that you will return the device at the completion of the intervention period. Any questions or problems with the device need to be addressed with the principal investigator.

Statement of Fair Treatment and Respect
UNC Charlotte wants to make sure that you are treated in a fair and respectful manner. Contact the University's Research Compliance Office (704-687-3309) if you have questions about how you are treated as a study participant. If you have any questions about the actual project or study, please contact Kristin L. Daley (704-562-4827, kalamb@uncc.edu) or Dr. Virginia Gil-Rivas (704-687-4747; vgilriva@uncc.edu).

Participant Consent
I have read the information in this consent form. I have had the chance to ask questions about this study and about my participation in the study. My questions have been answered to my satisfaction. I am at least 18 years of age, and I agree to participate in this research project. I understand that I will receive a copy of this form after it has been signed by me and the principal investigator of this research study. I agree, through my signature on this consent, to keep confidential any participant information that I may hear through my participation.

_____ _____
Your Name (PLEASE PRINT) DATE

_____ _____
Your Signature DATE

_____ _____
Investigator Signature DATE

~ This form was approved for use on February 11, 2009 for use for one year. ~

APPENDIX D: Study Measures

Participant Information

Name: _____

Contact Information:
Phone number:
Email address:

Height:_____

Weight:_____

Blood Pressure:_____

Number of weekly minutes of exercise:_____

Marital status:_____

Gender:_____

Race:_____

Highest level of education completed:_____

Current job:_____

HADS

Choose the response that best describes your current feelings.

1. I feel tense or 'wound up' :

Most of the time	3
A lot of the time	2
From time to time, occasionally	1
Not at all	0

2. I still enjoy things I used to enjoy:

Definitely as much	0
Not quite so much	1
Only a little	2
Hardly at all	3

3. I get a sort of frightened feelings as if something awful is about to happen:

Very definitely and quite badly	3
Yes, but not too badly	2
A little, but it doesn't worry me	1
Not at all	0

4. I can laugh and see the funny side of things:

As much as I always could	0
Not quite as much now	1
Definitely not so much now	2
Not at all	3

5. Worrying thoughts go through my mind:

A great deal of the time	3
A lot of the time	2
From time to time, but not too often	1
Only occasionally	0

6. I feel cheerful:

Not at all	3
Not often	2
Sometimes	1
Most of the time	0

7. I can sit at ease and feel relaxed:

Definitely	0
Usually	1
Not often	2
Not at all	3

8. I feel as if I am slowed down:

Nearly all the time	3
Very often	2
Sometimes	1
Not at all	0

9. I get a sort of frightened feelings like ‘butterflies’ in the stomach:

Not at all	0
Occasionally	1
Quite often	2
Very often	3

10. I have lost interest in my appearance:

Definitely	3
I don’t take as much care as I should	2
I may not take quite as much care	1
I take just as much care as ever	0

11. I feel restless as I have to be on the move:

Very much indeed	3
Quite a lot	2
Not very much	1
Not at all	0

12. I look forward with enjoyment to things:

As much as I ever did	0
Rather less than I used to	1
Definitely less than I used to	2
Hardly at all	3

13. I get sudden feelings of panic:

Very often indeed	3
Quite often indeed	2
Not very often	1
Not at all	0

14. I can enjoy a good book or radio or TV program:

Often	0
Sometimes	1
Not often	2
Very seldom	3

ISI

Please answer each of the questions below by circling the number that best describes your sleep patterns ***in the past week***. Please answer all questions.

Please rate the current (past week's) **SEVERITY** of your insomnia problem(s):

	None	**Mild**	**Moderate**	**Severe**	**Very Severe**
Difficulty falling asleep	0	1	2	3	4
Difficulty staying asleep	0	1	2	3	4
Problem waking up too early	0	1	2	3	4

How **SATISFIED/DISSATISFIED** are you with your current sleep pattern

Very Satisfied	**Satisfied**	**Neutral**	**Dissatisfied**	**Very Dissatisfi**ed
0	1	2	3	4

To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. Daytime concentration, memory, mood, etc.)?

Not at all Interfering	**A little**	**Somewhat**	**Much**	**Very Much Interfering**
0	1	2	3	4

How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all Noticeable	**A little**	**Somewhat**	**Much**	**Very much noticeable**
0	1	2	3	4

How **WORRIED/DISTRESSED** are you about your sleep problem?

Not at all worried	**A little**	**Somewhat**	**Much**	**Very Much Worried**
0	1	2	3	4

Total _____

PSQI

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

   BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

   GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you…

a) Cannot get to sleep within 30 minutes

Not during the past month____	Less than once a week____	Once or twice a week____	Three or more times a week____

b) Wake up in the middle of the night or early morning

Not during the past month____	Less than once a week____	Once or twice a week____	Three or more times a week____

c) Have to get up to use the bathroom

Not during the past month____	Less than once a week____	Once or twice a week____	Three or more times a week____

d) Cannot breath comfortably

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

e) Cough or snore loudly

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

f) Feel too cold

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

g) Feel too hot

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

h) Had bad dreams

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

i) Have pain

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

j) Other reason(s), please

describe_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good_____

Fairly bad _____

Very bad_____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month____	Less than once a week____	Once or twice a week____	Three or more times a week____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all	_____
Only a very slight problem	_____
Somewhat of a problem	_____
A very big problem	_____

10. Do you have a bed partner or roommate?

No bed partner or roommate	_____
Partner/roommate in other room	_____
Partner in the same room, but not same bed	_____
Partner in same bed	_____

CSES

When things aren't going well for you, or when you're having problems, how confident or certain are you that you can do the following:

Cannot do at all					Moderately certain can do					Certain can do
0	1	2	3	4	5	6	7	8	9	10

For each of the following items, write a number from 0-10, using the scale above.

When things aren't going well for you, how confident are you that you can:

1. Keep from getting down in the dumps. ____
2. Talk positively to yourself. ____
3. Sort out what can be changed, and what cannot be changed. ____
4. Get emotional support from friends and family. ____
5. Find solutions to your most difficult problems. ____
6. Break an upsetting problem down into smaller parts. ____
7. Leave options open when things get stressful. ____
8. Make a plan of action and follow it when confronted with a problem. ____
9. Develop new hobbies or recreations. ____
10. Take your mind off unpleasant thoughts. ____
11. Look for something good in a negative situation. ____
12. Keep from feeling sad. ____
13. See things from the other person's point of view during a heated argument. ____
14. Try other solutions to your problems if your first solutions don't work. ____
15. Stop yourself from being upset by unpleasant thoughts. ____

CSES

When things aren't going well for you, or when you're having problems, how confident or certain are you that you can do the following:

Cannot do at all					Moderately certain can do					Certain can do
0	1	2	3	4	5	6	7	8	9	10

For each of the following items, write a number from 0-10, using the scale above.

When things aren't going well for you, how confident are you that you can:

16. Make new friends. ____
17. Get friends to help you with things you need. ____
18. Do something positive for yourself when you are feeling discouraged. ____
19. Make unpleasant thoughts go away. ____
20. Think about one part of the problem at a time. ____
21. Visualize a pleasant activity or place. ____
22. Keep yourself from feeling lonely. ____
23. Pray or meditate. ____
24. Get emotional support from community organizations or resources. ____
25. Stand your ground and fight for what you want. ____
26. Resist the impulse to act hastily when under pressure ____

ATQ-30

Read each item below, and rank how frequently (if at all) each thought occurred to you over the last week. Use the following scale:

1	2	3	4	5
Never/Rarely	Infrequently	Sometimes	Moderately	Frequently

1.	I feel like I'm up against the world.	1	2	3	4	5
2.	I'm no good.	1	2	3	4	5
3.	Why can't I ever succeed?	1	2	3	4	5
4.	No one understands me.	1	2	3	4	5
5.	I've let people down.	1	2	3	4	5
6.	I don't think I can go on.	1	2	3	4	5
7.	I wish I were a better person.	1	2	3	4	5
8.	I'm so weak.	1	2	3	4	5
9.	My life's not going the way I want it to.	1	2	3	4	5
10.	I'm so disappointed in myself.	1	2	3	4	5
11.	Nothing feels good anymore.	1	2	3	4	5
12.	I can't stand this anymore.	1	2	3	4	5
13.	I can't get started.	1	2	3	4	5
14.	What's wrong with me?	1	2	3	4	5
15.	I wish I were somewhere else.	1	2	3	4	5
16.	I can't get things together.	1	2	3	4	5
17.	I hate myself.	1	2	3	4	5
18.	I am worthless.	1	2	3	4	5
19.	Wish I could just disappear.	1	2	3	4	5
20.	What's the matter with me?	1	2	3	4	5
21.	I'm a loser.	1	2	3	4	5
22.	My life is a mess.	1	2	3	4	5
23.	I'm a failure.	1	2	3	4	5

24. I'll never make it.	1	2	3	4	5
25. I feel so hopeless	1	2	3	4	5
26. Something has to change.	1	2	3	4	5
27. There must be something wrong with me.	1	2	3	4	5
28. My future is bleak.	1	2	3	4	5
29. It's just not worth it.	1	2	3	4	5
30. I can't finish anything.	1	2	3	4	5

PSS

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate by circling the appropriate number how often you felt or thought a certain way.

0=never 1=almost never 2=sometimes 3=fairly often 4=very often

1. In the last month, how often have you been upset because of something that happened unexpectedly? 0 1 2 3 4

2. In the last month, how often have you felt that you were unable to control the important things in your life? 0 1 2 3 4

3. In the last month, how often have you felt nervous and "stressed"? 0 1 2 3 4

4. In the last month, how often have you felt confident about your ability to handle your personal problems? 0 1 2 3 4

5. In the last month, how often have you felt that things were going your way? 0 1 2 3 4

6. In the last month, how often have you found that you could not cope with all the things that you had to do? 0 1 2 3 4

7. In the last month, how often have you been able to control irritations in your life? 0 1 2 3 4

8. In the last month, how often have you felt that you were on top of things? 0 1 2 3 4

9. In the last month, how often have you been angered because of things that were outside of your control? 0 1 2 3 4

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? 0 1 2 3 4

LOCI

Following is a series of attitude statements. Each represents a commonly held opinion. There are no right or wrong answers. You will probably agree with some items and disagree
with others. We are interested in the extent to which you agree or disagree with such matters of
opinion.
Read each statement carefully. Then indicate the extent to which you agree or disagree using the following responses:

-3	-2	-1	+1	+2	+3
Strongly Disagree	Somewhat Disagree	Mildly Disagree	Mildly Agree	Somewhat Agree	Strongly Agree

1. Whether or not I get to be a leader depends mostly on my ability. _____
2. To a great extent my life is controlled by accidental happenings. _____
3. I feel like what happens in my life is mostly determined by powerful people. _____
4. Whether or not I get into a car accident depends mostly on how good a driver I am. _____
5. When I make plans, I am almost certain to make them work. _____
6. Of ten there is no chance of protecting my personal interests form bad luck happenings. _____
7. When I get what I want, it is usually because I'm lucky. _____
8. Although I might have good ability, I will not be given leadership responsibility without appealing to those positions of power. _____
9. How many friends I have depends on how nice a person I am. _____
10. I have often found that what is going to happen will happen. _____
11. My life is chiefly controlled by powerful others. _____
12. Whether or not I get into a car accident is mostly a matter of luck. _____
13. People like myself have very little chance of protecting our personal interests when they conflict with those of strong pressure groups. _____
14. It's not always wise for me to plan too far ahead because many things turn out to be a matter of good or bad fortune. _____
15. Getting what I want requires pleasing those people above me. _____
16. Whether or not I get to be a leader depends on whether I'm lucky enough to be in the right place at the right time. _____
17. If important people were to decide they didn't like me, I probably wouldn't make many friends. _____
18. I can pretty much determine what will happen in my life. _____
19. I am usually able to protect my personal interests. _____
20. Whether or not I get into a car accident depends mostly on the other driver. _____
21. When I get what I want, it's usually because I worked hard for it. _____
22. In order to have my plans work, I make sure that they fit in with the desires of people who have power over me. _____
23. My life is determined by my own actions. _____
24. It's chiefly a matter of fate whether or not I have a few friends or many friends. _____

The PANAS

This scale consists of a number of words that describe different feelings and emotions. Read each item and then mark the appropriate answer in the space next to that word. Indicate to what extent you are feeling *at this very moment.*

Use the following scale to record your answers.

1	2	3	4	5
very slightly or not at all	a little	moderately	quite a bit	extremely

_____interested	_____irritable
_____distressed	_____alert
_____excited	_____ashamed
_____upset	_____inspired
_____strong	_____nervous
_____guilty	_____determined
_____scared	_____attentive
_____hostile	_____jittery
_____enthusiastic	_____active
_____proud	_____afraid

BENCH-STEP DATA SHEET

Name: _____ Age: _____ Date: _____

Weight: ____lb _____kg Actual or Predicted Max Heart Rate (HR): _____bpm

<table>
<tr><th colspan="5">Test Data</th></tr>
<tr><td rowspan="2">Pre-Exercise</td><td>HR (bpm)</td><td colspan="2">BP (mmHg)</td><td rowspan="4">Comments:</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td colspan="4">Exercise
Perform bench-step exercise on a bench 16.25” high for 3 minutes at a step rate of 24 steps per minute for men and 22 for women.</td></tr>
<tr><td rowspan="2">Recovery</td><td>HR_{15sec}</td><td>HR_{REC} (HR_{15sec} * 4) (bpm)</td><td>BP (mmHg)</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>

Calculations to Predict VO_{2max} From Bench-Step Data
HR_{REC} = recovery heart rate expressed as bpm
Men VO_{2max} = 111.33 – (0.42 * HR_{REC} _____) = _____ ml * kg^{-1} * min^{-1}
Women VO_{2max} = 65.81 – (0.1847 * HR_{REC} _____) = _____ ml * kg^{-1} * min^{-1}

Sleep Log
(accompanies actigraph)

	Night One	Night Two
What time did you go to bed?		
How many minutes did it take you to fall asleep?		
How many hours of sleep did you get?		
How many times did you wake up?		
How long were you awake during the night?		
Did you sleep with a bed partner?		
What time did you wake up?		
Was this a typical or unusual night for you?		

Appendix E: EBCT FEEDBACK QUESTIONNAIRE

EBCT Feedback

Thank you so much for participating in the EBCT study! As I am finishing the write-up of the study, I would really love to have some feedback on what you liked and did not like about the study. I have included a self-addressed stamped envelope for the feedback, so please feel free to be as open in your responses as possible!

1. How likely would you be to participate in a stress reduction program like EBCT again?

   Very likely Not at all

   10 9 8 7 6 5 4 3 2 1

2. What did you like most about the program?_____

   _____

   _____

   _____

3. What did you like the least?_____

   _____

   _____

   _____

4. What suggestions do you have for the program?_____

   _____

   _____

   _____

5. Did you start exercising more as a result of the program? Yes No

   How many minutes?_____

6. Do you think the sessions helped? Yes No Not Sure

   Why or why not?_____

   _____

   _____